

An Integral Treatment Paradigm (ITP) in the Treatment of Cancer: A Randomized Controlled Trial Plus Qualitative Analysis, Using Mind-Body Medicine and Energy Medicine to Bolster the Emotional, Functional, Physical and Social Dynamics of Cancer Patients

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Abstract

Focus: This study investigated the use of an Integral Treatment Paradigm (ITP), per Ken Wilber's integral theory as its treatment principle for treating the symptoms and discomfort associated with cancer.

Approaches: Cancer affects many levels of a person's being. ITP draws on Mind-body medicine and Energy medicine for its therapies. ITP concentrates on treating the mind of the person first rather than just focusing on the physical disease, followed by an education program of self-care and self-empowerment designed to reinvigorate the self-healing processes of the patient. A protocol of meditative Qigong helps the patient to produce endogenous qi for self-healing and self-empowerment.

Design: A randomized controlled trial was conducted to assess the effect of a six-week ITP intervention program for patients with breast cancer. Thirty-six patients were randomly assigned to either an intervention group or a wait-list control group. A Functional Assessment of Cancer Therapy questionnaire - General version 4 (FACT-G) was used to measure quality of life (QOL) of patients relating to emotional well-being (EWB), functional well-being (FWB), physical well-being (PWB), and social well-being (SWB) at baseline and at end of ITP treatment. The outcomes of the intervention group and the control group were compared and analyzed both quantitatively and qualitatively.

Major Findings: Results showed that patients in the intervention group achieved significant improvement in QOL scores as compared with those in the control group. The mean difference was 15.19, $t(34)=4.48$, $p<0.001$.

Implications: The findings of this study suggest that an Integral Treatment Program is helpful to deal with the multi-layered problems and demands of the cancer patient.

Key Words: breast cancer, Integral Treatment Program, ITP, Qi, meditation

Introduction

Cancer is a chronic disease. The heterogeneity of its causes complicates diagnosis and treatment (Greenwald & Dunn, 2009). In recent years, significant advances have been made in cancer research which have shed light on the etiology of cancer. Scientists are now able for the first time to decipher the intricate interplay of cellular genes and regulatory genetic elements that are responsible for the development of the cancer we see in clinical practice (Urruticechea, Alemany, Balart et al., 2010). This has been made possible by the development of sophisticated techniques in genomics, proteomics (the entire complement of proteins that is or can be expressed by a cell, tissue, or organism), and bioinformatics. Meanwhile, the design and development of anti-cancer drugs over the years have made possible new cancer therapies, such as adjuvant and targeted therapies to be applied for the treatment of cancer (Sudhakar, 2009). However, despite occasional successes, no panacea for cancer has been found, and successful treatment of all types of cancer is still a long way from reality.

The main reason for this difficulty is that cancer results from the uncontrolled multiplication of subtly modified normal human cells (Oliver, Hussain, et al., 2004). The majority of drugs used for treatment of cancer today are cytotoxic drugs that work by interfering with the operation of the DNA of all cells. Cytotoxic drugs have the potential to be very harmful to all body systems and to produce undesirable and uncomfortable side effects unless they are applied specifically to cancer cells in focused ways (Sudhakar, 2009). Patients who undergo general cytotoxic drug treatment often report nausea, vomiting, pain, hair loss, fatigue and, to a certain extent, mild cognitive impairment because these drugs interfere with the functions of cells in many parts of the body.

Living with cancer can exact an emotional toll on the patient who, more often than not, suffers from anxiety and depression (Cardoso, Graca, et al., 2015). These symptoms are often worsened by the side effects of chemotherapy.

A growing number of cancer patients have turned to complementary therapies as supportive interventions to alleviate their pain and emotional traumas. Healing Touch, Therapeutic Massage and Mindfulness Meditation are examples of such interventions. Over the years, substantial numbers of clinical studies have been conducted by research institutes, universities, and hospitals using complementary therapies to treat cancer patients to reduce pain, fatigue and insomnia associated with the treatment of chemotherapy. Reports of such clinical studies are published by the U.S. National Institute of Health (ClinicalTrials.gov).

A review of the studies published in PubMed shows that most clinical trials were conducted on patients using a single therapy to deal with a particular problem, as, for example, with therapeutic massage for relief of pain, or mindfulness meditation for alleviation of distress and anxiety. Complementary therapies are rarely coordinated, and applied in combination as an integral therapy for the treatment of cancer.

This study seeks to determine if using a treatment paradigm consisting of a number of customized mind-body medicine and energy medicine complementary therapies, properly coordinated and integrated, can produce a multiplier treatment effect when applied synergistically to cancer patients.

An integral treatment paradigm (ITP)

The causes of a chronic disease such as cancer are multifactorial. They may include feelings, emotions, and belief systems as well as physical, mental and spiritual dimensions of a person, all of which are always intertwined. Most treatment strategies for cancer, whether conventional, complementary or alternative, tend to concentrate on the disease rather than on the plights of the patients themselves. What is urgently needed is a comprehensive strategy, designed for treating the 'person' first, before treating the disease. The treatment strategy should aim initially

at calming the mind of the patient, restoring his sense of confidence, and finally empowering him to take charge of his life, including taking charge of all treatment protocols for his disease.

This is not a new suggestion. Hippocrates observed, "It is far more important to know what sort of person has a disease than to know what sort of disease the person has." Sadly, much of modern medicine, and significant numbers of complementary therapists overlook this important observation

The ITP adopts Kent Wilber's integral theory as its treatment principle and draws on Mind-body medicine and Energy medicine for its therapies. ITP concentrates on treating the mind of the person first, rather than the disease. This is followed by an education program in self-care and self-empowerment, designed to invigorate the self-healing process of the patient.

The central tenet of Wilber's integral philosophy consists of a comprehensive view of reality. In Wilber's opinion "the word integral means comprehensive, inclusive, non-marginalizing, embracing, Integral approaches to any field attempt to do exactly that: to include as many perspectives, styles and methodologies as possible within a coherent view of the topic. In a certain sense, integral approaches are 'meta-paradigms', or ways to draw together an already existing number of separate paradigms into an interrelated network or approaches that are mutually enriching" (Wilber in Visser, 2003).

Wilber postulates that all phenomena can be organized into four quadrants, which are formed by interfacing the two dichotomies of individual versus collective and the dimensions of interior versus exterior. The four quadrants of Wilber's integral model are represented in Figure 1.

Figure 1. A simplified version of Wilber's four-quadrant integral model

<p>"I"</p> <p>Interior of Individual (Subjectivity) Beliefs Thoughts Feelings Concepts</p>	<p>"IT"</p> <p>Exterior of Individual (Objectivity) Tissues Cells Molecules Atoms</p>
<p>"WE"</p> <p>Interior of Collective (Intersubjectivity) Common language Shared cultural beliefs Shared values Shared worldviews</p>	<p>"ITS"</p> <p>Exterior of Collective (Interobjectivity) Groups, Families Social structures National states Ecosystem</p>

In the realm of health care, the Integral model provides a powerful tool for conceptualizing life and human experience in health and healing. It can be used in investigating the multifactorial nature of disease, and provides a framework for different treatment modalities in a coordinated and coherent paradigm for best possible healing outcome (Astin & Astin, 2002)

ITP adopts this integral approach to the treatment of cancer, because it combines a wide range of approaches that include the elements of mind-body intervention, human cell biology, quantum mechanics, bioenergy healing, meditation and meditative Qigong for the treatment of cancer patients.

Mind-body medicine

The first component of ITP is Mind-body medicine. Emerging evidence during the past decades suggests that psychological factors can directly influence physiological functions and healing outcomes (Schneiderman, et al,2005; Linton, et al, 2011). Psychoneuroimmunology and the relationship between emotions, immune regulation, and gene expression are also examined in the context of cancer control and treatment (Pert et al, 2005). In this regard, some of the recent scientific advances in psychological, social and biological processes have been incorporated in ITP for treatment of cancer.

Energy medicine is the second component of ITP. Energy Medicine addresses energy fields surrounding and interpenetrating a person's body, to stimulate healing, restore balance in the body and promote wellness. Such therapeutic approaches have often been regarded by conventional medicine with a great deal of skepticism. Modern studies of bio-electromagnetism have documented that there is an energy field surrounding the human body (Becker,1990). Over the last decades, scientists have developed measurable connections between these biological energy fields and states of health and illness

Methods have also been developed to measure subtle energy fields, outside the spectrum of bio-electromagnetism, within and around the human body (Rubik,2016). Scientists are beginning to explore and postulate the biophysical mechanisms that enable therapists to manipulate energy fields for the benefit of their patients.

Qi, a potent healing energy

Among the various types of energy that emit a weak electromagnetic wave, Qi is a preferred candidate in energy medicine to be used for a new approach in cancer treatment. The concept of Qi has verifiable properties in science and also an esoteric connection in subtle energy (Stump, 2011). William Tiller (2007) has discussed Qi in terms of electromagnetic energy and has shown how this subtle energy responds to human intention. Research undertaken by Cyril Smith (2011) shows that the living systems make use of frequencies and fields for healing, which include time variations of electric fields and magnetic fields, plus piezoelectrical radiation and mechanical vibrations. On the scientific aspects of Qi, James Oschman concludes that "semiconduction of electrons through the collagen matrix, the migration of protons through the water matrix, and the clouds of mobile electrons....are just a few of the possible biophysical mechanisms that could account for aspects of vital energy, prana or qi in living systems" (Oschman, 2011).

A study by Seto (Seto et al 1992) in Japan confirms 'a large biomagnetic field emanated from the hands of practitioners of a variety of healing and martial arts techniques, including Qigong, yoga and meditation. The concept of Qi could therefore be easily understood and accepted by a wide spectrum of people in the West and the East.

Qi, an energetic concept in Traditional Chinese Medicine, has been translated to refer to the flow of energy, spirit, or breath that animates living entities. In fact, the natural properties of Qi are complex, and have not been fully understood by many. It is not a biophysical force but rather a psycho-biophysical one, mixed with intentions. The Chinese consider the basic substances such as Essence (Jing), Energy (Qi), and Spirit (Shen) as part and parcel of an energetic system in which various substances interact to generate the whole of a living organism.

Qi as a form of subtle energy is said to exist in both particle and wave forms. As particles, qi possesses qualities suggesting those of free and delocalized clouds of mobile electrons that can migrate through the semiconducting living matrix and reach every nook and cranny of the body, or travel along defined channels in the meridian to every cell, tissue and organ of the body system. As electromagnetic waves, they display quantum properties, such as biological coherence and vibration, and may produce non-local effects such as distant healing. Because qi is observed in acupuncture (Ji-Eun Park. et al, 2013), as well as in its derivatives of shiatsu (Stefanini, 2011) K and Kinesiology (Posadzki P., et al 2010) with a pervasive reach to the full spectrum of biological processes and physical conditions of the entire body.

For decades, Qigong and acupuncture practitioners have been using Qi as a complementary therapy, along with conventional medicine, to treat cancer, with varying degrees of success. In spite of the potency of Qi as a healing agent for a broad spectrum of physical and psychological problems, and advances being made in the field of energy medicine in recent years, no substantial breakthrough has been made in the treatment of cancer. A re-examination of our understanding of cancer and our relative treatment strategy is still urgently needed.

A new understanding of cancer

Do we understand cancer? No, nobody does. There is something missing. Our real problem is not "What is cancer?" but "What is life?" We can't understand cancer until we understand life, because cancer is just distorted life.

- Albert Szent-Gyorgyi (1978)

Albert Szent-Gyorgyi wrote from his experience of witnessing both his beloved wife and his only daughter die of cancer. He was able to narrate a penetrating and insightful story of what life was like with cancer. More often than not, cancer patients live in constant fear, worry and depression. Continuous biomedical treatments completely distort their normal life and deprive them of their joy of waking up to a new tomorrow. Some lapse into a state of helplessness and hopelessness .

A novel treatment strategy

Acknowledging the desperate situation of cancer patients, a novel treatment strategy has been introduced by the author, using Qi as a gentle, yet pervasively potent power for healing. The strategy is divided into three stages.

Stage1. Harmonize and regulate the mind, (tiao xin) the body (tiao Xing) and the breath (tiao xi). The first stage concentrates on treating the mind, calming the emotional upheaval of the patient, and instilling a sense of control and normalcy in the mind. This has the added advantage of strengthening the natural resistance, recuperative, and healing powers of the body. A protocol of breathing techniques further helps the body to relax and regain balance and physical strength in its fight against cancer. Program: The treatment modality to be used in Stage 1 is a special form of meditative Qigong.

For millennia, the Chinese Taoists have been practicing Qigong (literally translated as "Life Energy Cultivation") to unleash, strengthen, and direct endogenous Qi within the body to foster health and cure disease at all levels of the human organism. With roots in Taoist and Buddhist philosophy, Chinese medicine, and martial arts, there is a diverse spectrum of Qigong forms. The different types of Qi Gong being practiced today range in the thousands.

Meditative Qigong is a simple but very effective tool. It is a special form of exercise and meditation for the cultivation of Qi and has been used in therapeutic settings either as a sole therapeutic technique or as a complementary therapy to conventional medicine. It has shown significant clinical effects in the cure of chronic diseases such as hypertension, coronary heart disease, gastric and duodenal ulcers, asthma, diabetes, and malignant tumor (Ma, 1992).

The Chinese regard "Shen" (the spirit), as the source of life. It comprises two main elements: Yuan Shen (original spirit) and Shi Shen (consciousness). Yuan Shen is mainly understood as the power at the origin of all processes of life and is our original endowment. In a more common context, it is the spirit that gives the human heart/mind its clear-sightedness and intelligence (Vallee, 2012). Shi Shen refers to the knowledge acquired through consciousness. It includes the feeling or knowledge acquired through the senses. It also includes the rational forms of knowledge acquired through concepts and ideas as well as intellectual processes performed on all these types of knowledge, such as analyzing, synthesizing, judging, associating, inventing, and so on (Mo, W. D. 1993). When these two elements are in balance, life is in harmony. Excesses of emotions such as anger, worry, sorrow, fear, joy, or of thought mean that Shi Shen (consciousness) is interfering with the natural regulating powers of life. Disease is the natural consequence.

Practicing meditative Qigong will restore balance to the Yuan Shen and Shi Shen of the patient. This process of regulating the mind (tiao xin) is assisted by a program of gentle exercises to strengthen the body (tiao xing), along with diaphragmatic breathing (tiao xi) to stimulate the flow of vital energy through the meridians to foster a general state of relaxation of the body. When the body is completely relaxed, the person is ready to be healed.

Stage 2. Participate in an Integral Healing

The second stage engages the patient in the healing process. Healing is a multi-layered process. It implies a balance of the body, mind, and spirit. Intention is an important element in healing. Meditative Qigong, practiced with focused intention often produces positive healing results for cancer.

The proposed integrated healing program to be taught to cancer patients comprises elements of mental and spiritual orientation, intention and visualization, and medical Qi Gong. A central aspect of the program is the emphasis on the cultivation of love, compassion and forgiveness within the mind, self-awareness and self-care for the body, and an expanded view of the world and the universe. Such an orientation can give patients an enlightened awareness of their own humanity and spiritual support in times of adversity.

Thought and visualization are further important tools for healing. There are various definitions for thought, intent, intention and intentionality (Schlitz, 2003; Zahourek, 2011). In this context, no distinction is made in the meaning of these words. They are defined as a focused, purposeful mental activity that is directed at an outcome. Similarly, patients can trigger an electrical process in their nervous systems as they hold a focused and sincere intention for healing. "To the extent that religious, moral or therapeutic disciplines succeed, a person's many wills tend to become one will, single but articulated. Like a body in which each muscle functions in coordination with other body parts while retaining its own integrity, a well-articulated self can harmonize its separate volition to achieve its deepest ends" (Murphy, 1992).

Program: When the required outcome is visualized, together with a focused intention, the healing process is activated and can potentially elicit a local and systemic cascade of regulatory, restorative, reparative and regenerative processes.

Clinical experience has shown that rapid and complete spontaneous remissions can and do happen, even for the most potent cancers or for the most catastrophic injuries" (Oschman, 2003; Turner, 2014a; 2014b). Our challenges are to clarify what facilitates such remissions

In relation to stage two programs, a few important issues need to be explained. How do we generate endogenous Qi in the body? How can endogenous Qi be harnessed for healing? Qigong masters have been using Qi for treatment of cancer for decades. How does the use of Qi for healing in this program differ from that used by other practicing Qigong masters?

According to the Chinese Taoist healing traditions, Qi can be generated, mobilized and given direction by thought blending with three other activities of the mind and body. These include visualization, breathing, and Daoyin (body movements together with specific bodily postures). The body movements are designed to stimulate and regulate the flow of Qi throughout the meridian system and are considered an important part of Qigong.

A distinctive property of Qi generated endogenously, within a person's own body, is that it can be felt and that it moves within the body, thus producing an impact on both consciousness and the physiological dynamics of the person. Different individuals may experience the sense of Qi in varying intensities, from very subtle to very strong physical sensations. Some may experience involuntary movements and tingling of the body, limbs and extremities. Others may feel perceptions of light inside the body, increased sensitivity to sound, a feeling of lightness and shifts in perceptions of body image (Low, 2011).

The present program strategy uses meditative Qigong as the overriding method to harness Qi for healing. Other complementary modalities such as intention, visualization, breathing, and daoyin are coordinated to form a comprehensive treatment program. It is important for the patient to practice the healing program in a state of deep and concentrated meditation. When under a state of altered consciousness, a person is undisturbed by the perception of the mind and can respond to the flow of Qi within the body systems with an extraordinary sense of alertness.

The patients begin meditation with a focused intention and visualize achieving the desired healing outcomes. This very thought activates the flow of Qi within the meridians. With love and compassion, they will then observe the flow of Qi, feel its presence and gently direct the Qi to the areas of the body where treatment is needed (the cancer sites). Depending on the intensity of the Qi activation, the patient will soon feel a sensation of warmth or a feeling of numbness or a tingling at the cancer site. This phenomenon is called De Qi. It indicates that Qi has arrived and is spreading its therapeutic powers to the cancer site. In this second phase of treatment, all the patients need to do is to mentally observe what is happening at the cancer site. This observation is important

How does this healing program differ from that of traditional Qigong masters? A traditional Qigong practitioner uses exogenous Qi emitted from his palm for treatment of patients. Patients are a passive receivers of Qi and take no active part in their own healing process. They are not totally involved physically, mentally, and spiritually in their own transformations, but rely on an exogenous remedy for assistance. Neither do they understand the mechanics or mechanisms used in the healing process. Treatment is dependent on the availability of the Qigong master. The patients themselves are powerless without the Qigong master.

The present program aims at educating the patients to generate Qi from within themselves. They are completely involved and take charge of every stage of their own healing and transformation. They can generate Qi on demand, as long as they make time to meditate and are fully aware and totally familiar with the procedures of healing. As their conditions improve after practicing the program for a period of time, they are encouraged and motivated to engage in further practices, thus starting a virtuous circle of continuous treatment, which further improves their health. Meditation has no harmful effects and has no time limits for practice. By regularly practicing the program and consulting their mentor from time to time as required, they can meditate themselves back to health.

Stage 3. Transcendence

The final phase of ITP treatment is transcendence. Here, after a period of meditation, the patient enters into a state of stillness, an absolute peace and calmness of mind (ru jing). This is an advanced level of consciousness in which the division between subject and object ceases to

exist, the division between 'me' and 'not me' melts away, and one feels at one with the entire universe. Patients feel as if they have entered into a special zone where they transcend all earthly sufferings and become healed.

To the layman, this seems inexplicable. To conventional healthcare practitioners it may seem improbable. But cases abound of persons entering into a 'zone' while totally engaged in dance performance (Hunt, 1989), sports (Murphy & White, 1978), music, and the martial arts (Saotome, 1993). This is the state in which a person's body, mind, spirit are one. He is in a state of quantum transcendence.

In Stage 3, patients are empowered to take full charge of their own healing, while the practitioner will only assume a supporting role as a consulting partner in the process. This is the most critical stage in the healing process, as the success or failure of the program depends on it. Usually, this is the stage where maximum healing effect is achieved.

PROGAM: Qigong exercise, whether meditative Qigong or medical Qigong, must be practiced regularly, persistently and faithfully, without fail, day in and day out, for a substantial period of time in order to obtain the desired and anticipated healing effects. For cancer patients, three one hour practice sessions every day are recommended. This can take place in the morning, afternoon, and in the evening before sleep.

The normal practice duration recommended by Qigong masters is half to one hour per day. This practice duration is sufficient for relaxation meditation but inadequate for treatment of cancer. This is one of the reasons why some cancer patients find Qigong practices ineffective for cancer treatment.

The modular nature of ITP

ITP is designed in a modular form, with each session representing a module that can be practiced individually or in combination with other modules, as time, place, and other conditions permit. It takes approximately sixty minutes to complete a session. The sessions can be extended or repeated per patients' preferences without producing undesirable side effects. However, each incremental practice of ITP will yield handsome benefits for the participant in terms of relaxation of body, peace of mind, and blissfulness of spirit, in addition to other perceivable medical benefits.

Because of the modular nature of ITP, new modules can be added to existing ones or old modules can be replaced to take advantage of new innovations and developments in healing philosophy and modalities.

Keys to success ITP practice

It would be rare for this paradigm to disappoint any participant who is willing to follow the program and practice diligently every day. The level of success varies by participant, depending on the following factors:

1. Mental resolve to take control of his life and healing.
2. Adherence to a strict ritual of daily practice without fail.
3. Perseverance and undaunted courage to face challenges such as pain, bodily discomfort and weakness associated with his disease during practice.
4. Spiritual faith and confidence in the ultimate triumph of his self-healing efforts.

The ITP program for cancer has incorporated a number of potent strategies from mind-body medicine and energy medicine in an integrated program of action. Strategies, however, are but secondary factors that help in the process of healing. On activating the process of spontaneous healing, Andrew Weil (1985) remarked that "all the circuitry and machinery is there: the problem is simply to discover how to turn on the right switches to activate the process".

In an article entitled "Spontaneous/Radical Remission of Cancer: Transpersonal results from a Grounded Theory Study," Kelly A. Turner (2014) listed six factors believed to be possible contributors to Radical Remissions of cancer. These are:

1. Diet change
2. Deepening spirituality
3. Increasing happiness
4. Releasing suppressed emotions
5. Taking supplements
6. Using intuition.

In regard to causes of spontaneous remission, it is hypothesized that we as human beings are shaped by the thoughts we think, the emotions we feel, and the actions we take. The ultimate belief is the belief in oneself. Once this is realized, it opens us up to infinite possibilities. Perhaps this is the ultimate source of the placebo effect, and the reason for spontaneous remissions in cancer and other chronic diseases.

Purpose of the Study

The purpose of this study was to develop ITP as a model program which addresses cancer at the sub-molecular level of the cell by using bioelectric and bioenergetic pathways of the living matrix to access the communication system of cancer cells, to restore normal control systems to cells that had developed overgrowth and mutation, and to restore apoptosis (the ordinary, periodic death of cells that occurs as a normal and controlled part of an organism's growth, development and normal biological functions).

It is recognized that the ITP model will take substantial time and resources to develop, test and refine to become recognized and accepted as an effective remedy for cancer. The immediate goal is, therefore, to use ITP in an experimental study to bolster the emotional, functional, physical and social dynamics of cancer patients. In this regard, the researcher, (the innovator and designer of the ITP program) conducted the study. Trained as a naturopath, the researcher has undertaken practical training in the care of cancer patients at the Penny Brohn Cancer Care Centre in England and has also been a Qigong practitioner for 20 years. He takes a simple, practical approach to the teaching of Qigong for beginners and is able to enthuse them to engage in regular Qigong practice for self-care and self-healing.

The randomized-controlled trial

A randomized-controlled trial was conducted between May and June, 2014 to study the effect of ITP on quality of life of cancer patients. Results were analyzed quantitatively and qualitatively.

Participants were recruited from a specialist breast cancer unit of the Guangdong Provincial Hospital, a teaching hospital of Guangzhou University of Chinese Medicine (GZUTCM) in Guangzhou, China. Inclusion criteria: Ambulatory medical oncology patients who had a confirmed diagnosis of breast cancer and had received chemotherapy. Exclusion criteria: A diagnosis of a major medical or psychiatric disorder, a history of epilepsy, brain metastasis, delirium, or medical contraindications for exercise. The research protocol was approved by the Institutional Review Board (IRB) of Akamai University.

Participants were randomly assigned manually by management of the oncology unit of the hospital to an intervention group and a wait-list control group. Those assigned to the intervention group received the usual medical care from the hospital and were invited to attend an Integral Treatment Program (ITP), comprising twelve 60 minute intervention sessions over a

period of six weeks. Participants assigned to the control group received the usual care from the hospital during the trial period but without the offer of the ITP program.

A total of 44 breast cancer patients were randomized, with 16 participants in the intervention group and 28 participants in the control group. Due to drop-outs, 36 participants were used for complete case analyses, with 15 participants from the intervention group and 21 participants from the control group. The demographic profile at baseline is summarized in Table 1.

Methods

Outcome measures for the study assessed the quality of life of the participants with the Functional Assessment of Cancer Therapy (General FACT-G, Version 4). This is a 27-item patient self-reported instrument designed to measure multidimensional quality of life (QOL) in cancer patients. FACT-G consists of four subscales assessing physical well-being (PWB), emotional well-being (EWB), social well-being (SWB) and functional well-being (FWB), with higher scores reflecting better QOL. The questionnaires were administered to the intervention group before treatment at baseline (week 0), at mid-point (week 3) and again at the end of the study (week 6). Except for the mid-point measure, participants assigned to the control group completed the baseline and the final outcome measures in the same time frames as the intervention group. The average scores for all participants in the intervention and control groups were measured and compared at the baseline and at the end-point (week 6).

Table 1. Demographic characteristics of participants at baseline

	Intervention (n=15)	Control (n=21)
Mean age (SD)	54.4 (8.5)	55.3 (6.8)
Gender (%) Female	15 (100.0)	21 (100.0)
Marital Status (%)		
Never married	--	1 (5.0)
Currently married	13 (86.6)	19 (90.0)
Widowed	2 (13.4)	1 (5.0)
Ethnicity (%) Chinese	15 (100.0)	21 (100.0)
Educational Level (%)		
Secondary	8 (53.4)	17 (81.0)
Tertiary	7 (46.6)	4 (19.0)
Employment (%)		
Retired	4 (26.6)	4 (19.0)
Housewife	--	3 (14.3)
Currently employed	11 (73.4)	14 (66.7)
Religious Involvement (%)		
Yes	2 (13.0)	5 (24.0)
No	13 (86.6)	16 (76.0)
Primary Cancer Diagnosis (%)		
Breast cancer	15 (100.0)	21 (100.0)
Cancer Treatment (%)		
Completed	11 (73.0)	15 (71.5)
In progress	4 (27.0)	6 (28.5)

Data Analysis

Statistical analyses were conducted using IBM SPSS version 21.0. Only participants with complete data were included in the analysis. Descriptive statistics such as mean and standard deviation were computed for intervention and control groups, respectively. Independent sample t-tests were used to compare the differences in outcomes between intervention and control groups and statistical significance was assessed. Paired sample t-tests were used to compare the differences at different time points. All statistical significances were assessed at 5% level.

The outcome measurements at baseline, weeks 3 and 6 are summarized in Tables 2, 3 and 4. The Global Quality of Life (GQOL) scores were computed by summing up the individual subscale-scores for physical well-being, social well-being, emotional well-being and functional well-being. Table 2 shows that the GQOL and the four subscale-scores between the intervention group and the control groups were not statistically different at baseline: intervention mean 73.8, (SD) 15.4 and control mean 71.7, (SD)17.0, with $p \geq 0.709$ respectively.

Table 2. Baseline measurement of participants with Quality of Life (QOL) as measured by FACT-G¹

Variables	Mean(SD) Intervention (n=15)	Mean(SD) Control (n=21)	p
Physical well-being (PWB)	20.3 (5.2)	20.3 (4.5)	0.992
Social well-being (SWB)	21.1 (3.6)	20.2 (6.8)	0.620
Emotional well-being (EWB)	15.5 (3.7)	15.3 (3.9)	0.848
Functional well-being (FWB)	16.8 (4.6)	15.8 (6.0)	0.614
Global Quality of Life(GQOL)	73.8 (15.4)	71.7 (17.0)	0.709

Note 1. Higher scores reflect better QOL in FACT-G subscale

The week 3 outcome measurement of the intervention group, after participating in the ITP program is shown in Table 3. Compared with its baseline measurements (Table 2) there was appreciable but not statistically significant improvement in scores for all of the four subscales and in the global quality of life total score.

Table 3. Mid-point (Week 3) outcome measurement of intervention group

Variables	Mean(SD) Intervention(n=15)
Physical well-being (PWB)	22.6 (3.1)
Social well-being (SWB)	22.5 (3.6)
Emotional well-being (EWB)	18.5 (3.2)
Functional well-being (FWB)	19.3 (5.2)
Global Quality of Life (GQOL)	82.9 (12.0)

Table 4 compares the scores of the intervention group and the control group at week 6. All scores of the intervention group including the GQOL score and all the four subscale-scores were significantly higher at end-point as compared with those in the control group. The GQOL score of the intervention group was a mean of 91.0,(SD)9.2 as compared with that of the control group with a mean of 73.7, (SD)15.3 with $p \leq 0.001$.

Table 4. End-Point (week 6) outcome measurement of intervention and control groups

Variables	Mean(SD) Intervention (n=15)	Mean(SD) Control (n=21)	p-value
Physical well-being (PWB)	24.5 (2.9)	20.5 (4.5)	0.004
Social well-being (SWB)	23.7 (3.3)	18.9 (7.5)	0.015
Emotional well-being (EWB)	20.7 (2.0)	16.2 (3.7)	0.001
Functional well-being (FWB)	22.1. (3.5)	18.1 (5.4)	0.016
Global Quality of Life (GQOL)	91.0 (9.2)	73.7(15.3)	0.001

Table 5 compares the within-group differences and Table 6 the between-group differences in scores of the intervention and control groups on quality of life outcomes from baseline to end-point (week 6). In the within-group comparison, the Global Quality of Life Score (GQOL) and the four subscale scores of the intervention group all showed statistically significant improvement during the six weeks. Results were mixed in the control group. The GQOL, the emotional and physical sub-scores each showed some improvement but did not reach statistical significance. The functional sub-score showed a significant improvement with $p \leq 0.037$ and the social sub-score showed some deterioration but did not reach statistical significance with $p \leq 0.205$.

There was a major and significant difference in between group outcomes. The mean GQOL difference was 15.19, $t(34)=4.448$, $p \leq 0.001$, and the mean differences in the four individual sub-scores were also significant. These mean differences reflect that participants in the intervention group achieved across the board improvement in quality of life after six weeks of treatment. The mean difference from baseline for the intervention group was 17.21, 95% CI=10.49 to 23.94, $p \leq 0.001$. In contrast, participants in the control group did not achieve significant improvement in their quality of life with a mean difference from baseline 2.02, 95% CI=-1.80 to 5.84, $p \leq 0.283$.

Table 5. Within-group differences in the Intervention and Control groups on Quality of Life Outcomes from baseline to end-point (week 6), based on complete-case analysis

Variables	Intervention Group (n=15)		Control Group (n=21)	
	Mean Difference from Baseline (95% CL)	p	Mean Difference from Baseline (95% CL)	p
Physical well-being (PWB)	4.20 (2.21 to 6.19)	<0.001	0.21 (-1.61 to 2.03)	0.815
Social well-being (SWB)	2.54 (0.69 to 4.38)	0.011	-1.33 (- 3.45 to 0.79)	0.205
Emotional well-being (EWB)	5.13 (2.71 to 7.56)	<0.001	0.91 (-0.43 to 2.26)	0.173
Functional well-being (FWB)	5.34 (3.41 to 7.28)	<0.001	2.23 (0.15 to 4.32)	0.037
Global Quality of Life (GQOL)	17.21 (10.49 to 23.94)	<0.001	2.02 (-1.80 to 5.84)	0.283

Table 6. Between-group differences in the Intervention and Control groups on Quality of Life Outcomes from baseline to end-point (week 6), based on complete-case analysis

Variables	Mean difference between groups (95% CL)	t	df	p
Physical well-being (PWB)	3.99 (1.36 to 6.63)	3.080	34	0.004
Social well-being (SWB)	3.87 (1.00 to 6.73)	2.745	34	0.01
Emotional well-being (EWB)	4.22 (1.74 to 6.70)	3.460	34	0.001
Functional well-being (FWB)	3.11 (0.25 to 5.98)	2.206	34	0.034
Global Quality of Life (GQOL)	15.19 (8.25 to 22.13)	4.448	34	<0.001

To form a detailed picture of the progress made by participants of the intervention group during their 6 week program, their measurement results from baseline (week 0) to mid-point (week 3) and from mid-point (week 3) to end-point (week 6) were compared and contrasted. Table 7 shows the within group differences from baseline to week 3. The mean improvement in GQOL outcome was 9.08 95% CI: 4.92 to 13.25, $p \leq 0.001$. The mean physical, emotional and functional sub-scores all showed statistically significant improvement. The social sub-score showed some improvement but did not reach statistical significance, with $p \leq 0.07$.

Table 7. Intervention group within-group differences on Quality of Life Outcomes at Week 3, compared with Baseline (based on complete-case analysis)

Variables	Mean Difference (95% CI)	t	p
Physical well-being(PWB)	2.27 (0.35 to 4.18)	2.54	0.023
Social well-being(SWB)	1.35 (-0.17 to 2.87)	1.91	0.077
Emotional well-being(EWB)	3.00 (1.22 to 4.78)	3.62	0.003
Functional well-being(FWB)	2.47 (1.08 to 3.85)	3.82	0.002
Global Quality of Life(GQOL)	9.08 (4.92 to 13.25)	4.67	0.001

In Table 8, the within-group differences from mid-point week 3 to end-point week 6 were compared. The mean improvement in GQOL outcome was 8.13, 95% CI: 4.00 to 12.26, $p \leq 0.001$. The mean physical, emotional, and the functional sub-scores all showed statistically significant improvement from week 3 to week 6 at 5% level. The social sub-score showed some improvement but did not reach statistical significance with $p \leq 0.187$, although the overall improvement for the total 6 week period was statistically significant.

It was evident from the results in Tables 7 and 8 that participants in the intervention group experienced significant improvement in quality of life in all QOL subscales as early as week 3 after treatment. Further improvements were made during the following three weeks up to the conclusion of the ITP program at week 6. For the overall results at end-point, please refer to table 5.

Table 8. Intervention group within-group differences on Quality of Life Outcomes for week 6 as compared with week 3 (based on complete-case analysis)

Variables	Mean Difference (95% CI)	t	p
Physical well-being (PWB)	1.93 (1.01 to 2.86)	4.49	0.001
Social well-being (SWB)	1.18 (-0.65 to 3.01)	1.39	0.187
Emotional well-being (EWB)	2.13 (0.47 to 3.79)	2.76	0.015
Functional well-being (FWB)	2.88 (1.33 to 4.42)	4.00	0.001
Global Quality of Life (GQOL)	8.13 (4.00 to 12.26)	4.22	0.001

Qualitative Interpretation of subjective comments in the intervention group

The aim of this qualitative research was to investigate the subjective understanding, emotional experience and personal actions taken by a randomized group of breast cancer patients in their journey through their treatment process, starting from the day when they were diagnosed with breast cancer to the day of completion of this research .. Special attention was paid to the performance of each individual patient in the group during the six-week ITP program, their subjective assessment of the effectiveness of ITP in helping them to deal with the daily demands of the recovery from the disease and treatment, and the objective results each participant achieved after learning and practicing the ITP components.

Qualitative research, while done in a structured process, is by its very nature interpretive research. It is an extensive collection of detailed records concerning context, people, actions, and the perceptions of participants as a basis for inductive generation of an understanding of what was going on and their perceptions of how things worked out for them (Locke et al, 2010). Among the methods used in this qualitative research were interviews, observation and analysis of documentary material such as participants' notes and their written opinion about the ITP program.

Two interview methods were used, depending on the information to be obtained. The first was an unstructured interview, where participants were encouraged to talk about their life stories and about their feelings and emotions, hopes and fears, denial and final acceptance of their illness. The second was a semi-structured interview that used specific questions to guide the interview. Within the semi-structured interview, a group of open ended questions was used, as were the probes which were open ended or specific to the participants' comments, such as "would you tell me more about...?"

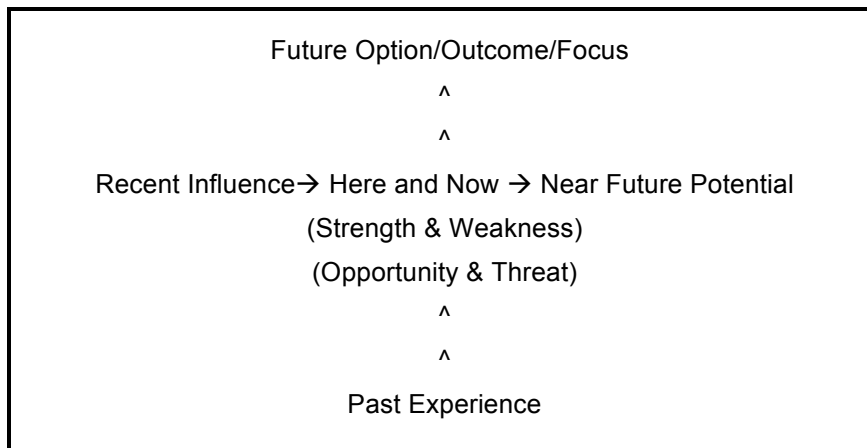
Questions included in the semi-structured interviews also explored their state of health in relation to their body, mind and spirit. The participants were asked to complete seven open questions directed to decipher their physical, mental and spiritual well-being. These questions corresponded to the seven major nerve plexus centers that are situated along the mid-line of the torso and are sometimes referenced as the seven major mid-line chakras of the body. These questions "...were intended to release any hidden and unresolved emotions and problems within each chakra" (Bulbrook, 2011).

1. What has happened to me? (Root chakra, the physical life circumstance)
2. I feel...? (Sacral chakra, emotion about self/physical body feelings)
3. My thoughts are...? (Solar Plexus, hunger and fulfillment /thinking)

4. My heart is...? (Heart chakra, connection with others)
5. I need to say...? (Throat chakra, speaking and listening /honor)
6. My future looks...? (Brow chakra, seeing and visioning)
7. Spiritually, I am...? (Crown chakra, spirituality and compassion)

Next, the participants were guided through a self-examination of their "personal matrix," in which they described how they saw themselves in the "here and now," the recent influences that impacted on their life, their near-future options and potentials, and their new focus, and their long-term future.

Figure 2. The Personal Matrix



It was relevant to this research that the participants proceeded from the central position of the "here and now," then worked their way through the vertical axis of their past experience, and on to future options/outcomes/focus. The horizontal axis provided additional insight and perspective on how other factors might have influenced recent thoughts and behaviors and what were the potentials of these influences

Within the context of the semi-structured interview the following methods were employed:

1. Develop a rapport with each participant by expressing a genuine interest in them as a person and in the information being shared.
2. Convey empathy and compassion.
3. Maintain a conversational flow.

Interviews were conducted in a safe and home-like environment so that participants felt greater ease and security in discussing sensitive issues. Data collection included speech and dialogue examples and participants' attitudes and understanding of issues. Further materials included personal notes, drawings, and pictures made by participants during the course of the 6-week lectures. At the end of the fifth week, participants were requested to reflect on what they had learned so far, and to what extent their new knowledge had affected their physical, mental and spiritual well-being. They were also asked, what, if any, were the unique features of the course, and what were their take-home ideas which had engendered a transformation of their attitudes, behavior and life perspectives. In addition, participants were invited to give feedback in a written report to be submitted at the conclusion of the course, by the end of week 6. In addition, if any participants had any problem or difficulty in verifying any aspects of their personal notes, they were welcome to present their notes for clarification. The personal notes and written reports of the participants constituted an invaluable documentary resource for analysis.

The raw details of this study were collected and edited in the form of individual cases, describing in detail the life history of each participant before contracting breast cancer, the way

she soldiered on through the surgery and chemotherapy treatment, her personal experience and the knowledge she gained in the 6 week program, and finally, her aspirations for the future.

To preserve the anonymity of individual participants in the final qualitative report, the identity and personal details of each participant were not revealed. The materials they shared, including their subjective understanding and emotions experienced in going through cancer; their comments on their experience with ITP; and personal actions taken during and after this study were assembled, correlated, and grouped as observations and comments of participants in the study for reference and general discussion.

Results of the qualitative study

A total of 15 breast cancer patients participated in the ITP program. They came from different age groups, diverse backgrounds and were at different stages of breast cancer. Although they achieved varying degree of success by the end of the program, they were happy with their experience and all expressed an earnest desire to participate in future programs to be organized by the researcher.

The performance of the participants can be grouped into four categories, by their responses to the treatment protocol:

1. The High Achievers distinguished themselves by their burning desire to strive for the best, their fighting spirit to overcome whatever difficulties faced them, and to achieve the goals they set for themselves in their fight against cancer. This group achieved the best results in their FACT-G scores.
2. The Effective Followers were patients who had established a mutual bond with their physicians in the course of their treatment. They followed the advice of their physicians to the letter, maintaining a healthy lifestyle, a balanced and optimistic mindset and participating in social activities to broaden their horizon and relationships with their peers. This group also scored well on their FACT-G assessments.
3. The Devout Believers had great religious faith and positive attitudes that embrace hope, love, trust, compassion and gratitude in their daily lives. They were unperturbed by the daily demands of cancer treatments, as they had peace of mind as they went through the treatment process. This group also had good FACT- G scores.
4. The Ordinary Performers had no special attributes in their personalities that made them unique, but they were genuinely interested in the ITP program. They were in the majority and all obtained satisfactory results in their FACT-G Scores

Finally, the combined effect of mind-body intervention and Qi Gong meditation awakened in the participants a desire to reconnect with families, friends and associates and led them to seek support and encouragement in their fight against cancer.

Discussion

The purpose of the study was to determine the effectiveness of an Integral Treatment Paradigm (ITP) designed to support the healing and recovery of 15 breast cancer patients over a period of six weeks. While the focus of this research was breast cancer patients, the ITP was originally designed for general application for all types of cancer patients and is sufficiently robust that it may be applied in that way.

Although an integral approach to the treatment of cancer is not new, a program that includes the elements of mind-body-spirit interventions has enormous benefits to offer people who have often, in their understanding, received a medical death sentence, and who are undergoing procedures that may be painful and severely debilitating.

While psychological approaches can often reduce the immediate emotional trauma of a cancer patient, the long-term solution in the support of emotional health is to help the participant to develop a peaceful mindset, a loving heart, and a healthy lifestyle with a balanced diet and regular, gentle exercises. These are the fundamental qualities that may provide support for the cancer patient and it is to be hoped will help in preventing any relapse of the disease.

Although ITP's individual components such as mind-body interventions, Qi meditation and Qi-Gong exercises are researched modalities, the way in which these modalities were used in combination in this study and for this cancer population was innovative. During the development of the ITP protocol, one of the key question was whether a treatment modality composed of disparate treatment therapies can produce a synergy of therapeutic effects for a disease as diverse in its range of challenges as cancer. Based on the results of this study, with the recognized limitation of the small sample size, ITP has been determined to be successful.

The results of this study have demonstrated that complementary medicine is useful in the treatment of cancer. It has also highlighted the importance of using a combination of therapies in an integral treatment paradigm for an effective and comprehensive treatment that catered to all of the needs of a patient's emotional, functional, physical and social requirements.

Potential applications of the ITP program in the light of this study

One of the major strengths of the ITP program is in its integral model. This model is effective in supporting the healing of the emotional trauma associated with cancer patient immediately the diagnosis.

While conventional oncologists are effective in organizing treatment protocols such as surgery, chemotherapy, and radiotherapy, they are not trained to recognize or deal with the emotional trauma associated with the cancer patient's sense of loss of self and the overall feeling of fear.

It is clear from the findings of this study that positive emotions and feelings have larger impacts on the cancer patient than are commonly anticipated by medical science. The Integral model is designed precisely to create an internal environment in which such positive emotions thrive and grow.

Integrally conscious and transformed ITP practitioners, who have personally experienced the ITP process as part of their training, will deal with patients' emotional response as one of the first priorities. Practitioners will support the bewildered, sad and depressed cancer patients with care, compassion and love. They will instill in the cancer patient's mind positive feelings of hope for the future, gratitude for their on-going life experience, and perspective where happiness is present in the here and now.

This positive shift in cancer patients' perceptions of reality will help them to move through what appear to be an unbearable and traumatic period of their lives, and to accept the current situation as a life experience which can be dealt with competently and from which they will move forward with inner growth rather than the utter devastation that they initially experienced. This positive attitude will greatly assist them in going through the treatment processes of surgery, chemotherapy and radiotherapy.

The ITP program practitioner seeks to educate, inspire and support the healing of the cancer patient during this challenging period of personal crisis. In so doing, there is a close bond established with the cancer patient. This relationship facilitates the transfer of knowledge, experience and skills to participants, while at the same time fostering mutual understanding, care, trust, and sharing of information.

A significant part of any healing process is about transformation. A transformed patient is a person filled with hope and a positive attitude. It could be said that happiness is generated from inside each individual. The ITP program is designed precisely to look at both the interior

emotional experience and the outside physical experience of the cancer patient in a systematic and coherent manner, in order to support the development and manifestation of the key moments of healing and transformation. This personal, life-to-life approach, is the hallmark of the ITP process, in contrast to the impersonal approach of biomedicine.

Another critical component of the ITP program is its educational program that addresses diverse subjects before using the ITP protocol. The education program gives the participant a general understanding of the philosophy, content and protocols involved in ITP. This information is delivered in a simple and easily understood style, with lots of practical examples and interesting video presentations. This renders the learning process an enjoyable experience. In addition, the educational component of ITP becomes an asset to the clinical staff, who then do not have to spend as much time explaining the individual components of the healing process to participants.

Another key element in the ITP program is the Qigong meditation, which is done on a daily basis. It is one of the most important aspects of the program. Focused intention and visualization are included in the Qigong meditation. The meditative process is calculated to synergize all the aspects of the program and produce a supportive and maximizing effect for all therapeutic inputs in the treatment program. For maximum effectiveness, the ITP program recommends that meditative Qigong should be practiced three hours daily. The long hours of practice will naturally reduce the time available for other social activities, but the increase in health benefit for the participants is demonstrated in the data results. One of the ways that meditative Qigong can be practiced without impinging on the normal activity of the patient is by scheduling the practice sessions in the morning, immediately after getting up, after lunch, and before retiring.

Limitations of the study

Although the statistical results were significant, several limitations of this study should be noted. This was the first time the ITP program was employed for treating breast cancer patients. Long term, the results will need to be correlated with results of additional studies, with larger participant sizes, using the same program protocols. The number of participants in the intervention group was relatively small (n=15). This was due to the limited financial resources available.

The study population was homogenous both in tumor type and the gender. It will be important to determine if the data are as significant with other types of cancer and more complex populations of cancer patients.

Another limitation of the study was the duration of the intervention. In the six weeks of the RCT there were two sessions each week. Two weeks (four sessions) were devoted to learning ITP and four weeks (eight sessions) were used for practicing. Participants were also asked to practice at home. Eight supervised practice sessions constituted an appreciably short period in which to assess the effectiveness of a treatment program which involves skills, experience, mental concentration and constant practice. While participants in this study were encouraged to continue their practice at home, a longer period of direct support may be more effective in developing sustained and enhanced positive emotional, spiritual and behavioral changes.

The ITP program's complexity is both a strength and a weakness. All of the different components of the ITP program are targeted to address a specific issue associated with a patient's experience of cancer. For example, in the ITP program, the mindfulness meditation is used to reduce pain, and a healthy diet in combination with gentle exercise are used to physically strengthen the body. While all of the individual therapies have been demonstrated to show individual effectiveness, further study of the full ITP program holds the potential for the development of greater insight and the development of targeted and effective protocols specific to the type of cancer for which the program is used.

Finally, since the qualitative research component of this study included interviews with participants, observation of the reactions and behaviors of participants, and documentary material submitted for review by the principal investigator, it is possible that both the experimenter effect and individual bias may have affected that portion of the reported results. Qualitative information in any study can also be affected by participants' expectations (placebo/expectancy effect) and social pressure for political correctness as a member of a group. However, parallel quantitative and qualitative protocol data analysis and compare and contrast techniques were used to promote a high degree of data accuracy.

While not part of this study, it is still tantalizing to speculate on some of the theoretical explanations for ITP. These may include mechanisms from quantum mechanics, and how modern electromagnetic and other principles attributed Qigong may bring about healings.

Summary

The initial positive findings of the current study support the ITP program and its inherent strength as a helpful intervention for cancer patients. There may be many more applications as well for ITP to promote the body's natural ability to heal from other diseases as well, through the combination of visualization, nutrition, focused intention and meditative Qigong. These methods can be practiced by patients in their own space and as frequently as time permits.

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