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**“Objective and Subjective Assessment of Qigong Related
Effects in Breast Cancer Patients”**

-A Feasibility Study -

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Master thesis of Traditional Chinese Medicine

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Master thesis proposal in Traditional Chinese Medicine (TCM) submitted to Instituto de Ciências Biomédicas de Abel Salazar – Universidade do Porto.

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ABSTRACT

Background: Breast cancer is one of the most prevalent cancers in industrialised countries. Research focuses more and more on the actual quality of life (QoL) including management of emotionality, side-effects of surgery and chemotherapy (CT).

Qigong exercises are an integral part of Traditional Chinese Medicine (TCM) and commonly used in cancer treatment. From a western standpoint they can be considered a self-treatment programme in terms of a traditional vegetative biofeedback therapy. Special exercises are traditionally chosen for emotional balance, fatigue, nausea and other key symptoms of chemotherapy.

One common scenario in everyday practice is that surgery is performed as a first intervention and chemotherapy is then planned to improve survival in severe cases to treat or prevent metastases. We chose patients whose surgical intervention was more than three months ago and for whom at this time point CT had been planned.

Objective: Evaluate the feasibility of an objective assessment of qigong-related effects on QoL and key symptoms of CT. If so, objective studies design can be developed to see if patients might profit from qigong therapy in terms of prevention of side-effects.

We also noticed that shoulder/arm mobility was often impaired in these patients as a consequence of prior surgery. Therefore we also assessed shoulder mobility.

Methods: Patients were evaluated using the WHOQoL questionnaire for cancer patients (QLQ-C30) and the respective module for breast cancer (QLQ-Br23).

Functional subscales evaluate (1)physical, (2)occupational, (3)emotional, (4)cognitive and (5)social impairment as well the (6)body image, (7)sexual functioning, (8)sexual pleasure and (9)future perspectives.

Furthermore, global health state and possible financial difficulties were evaluated.

The symptoms subscales evaluate (1)fatigue, (2)nausea and vomiting, (3)pain, (4)dyspnoea, (5)insomnia, (6)loss of appetite, (7)constipation, (8)diarrhoea, (9)systemic effects of therapy, (10)breast and (11)arm related symptoms and (12)possible hair loss.

Salivary cortisol levels were additionally determined as an objective parameter of stress.

Impairment of shoulder movement was assessed as mentioned above.

Patients were allocated to two groups: the qigong (N=11) received chemotherapy and qigong exercises, the control (N=5) received only chemotherapy. Self-training exercises by qigong were performed twice a week during five weeks.

Inclusion criteria: Aged > 18 years, physically fit for exercises, written consent, surgery free interval of at least 3 months, chemotherapy planned;

Exclusion criteria: Significant psychiatric complaints, medical contraindications;

Results:

1. In the qigong group all patients showed improvement of all scores of functional scales and global health as assessed by QLQ-C30 and QLQ-Br23.
The subscales cognitive functioning ($p=0,046$) and future perspectives ($p=0,046$) statistically significantly improved. However, in the control group virtually all scores worsened. In the global state of health sub scale we found a statistically significantly aggravation ($p=0,046$), a finding that we obviously prevent in qigong group although chemotherapy was applied.
2. The sub scale of symptoms tends to be improved in qigong group (not statistically significant). However in control group all symptoms tend to be worse. Even, pain ($p=0,05$) and loss of hair ($p=0,046$) aggravated statistically significantly.
3. Specific symptoms like nausea and vomiting appeared in both groups along the course of chemotherapy. In qigong group they did not aggravate statistically significantly. However in control group, nausea and vomiting, showed statistically significant aggravation ($p=0,035$).
4. Salivary cortisol levels diminished in almost all patients in both groups, although in qigong group was more pronounced (results not statistically significant).
5. The assessment of the shoulder/arm mobility surprisingly revealed that all patients of both groups suffered impairment of mobility and related complaints like pain and functional loss. Within the qigong group mobility increased significantly ($p=0,008$) and controls showed no significant change.

Discussion: The functional status and global health improved by qigong. We chose a specified sub-set of the so-called White Ball exercises based on the Heidelberg Model of Chinese Medicine. These exercises can therefore be recommended in the given scenario.

Concerning the methodology of this study, however, the general problem of adequate control groups within qigong studies shows the limits of conventional qigong study designs. Although the results are promising, continuation of the study increasing the number of cases is recommended.

Keywords: Breast cancer, chemotherapy, qigong, Heidelberg Model of TCM, quality of life.

RESUMO

Revisão da literatura: O cancro da mama é um dos cancros mais prevalentes nos países industrializados. Cada vez mais a investigação se tem centrado na qualidade de vida de doentes com cancro incluindo a gestão emocional, os efeitos secundários da cirurgia e quimioterapia.

O qigong é uma técnica integrante da Medicina Tradicional Chinesa usada no tratamento do cancro. Do ponto de vista ocidental, pode ser considerado como um programa de tratamento próprio tendo em conta a tradicional terapia de “biofeedback”. Exercícios específicos são escolhidos para controlo emocional, fadiga, náusea e outros sintomas típicos provocados pela quimioterapia.

Um cenário comum na prática diária é que a cirurgia é realizada como uma primeira intervenção e a quimioterapia é, então, planeada para melhorar a sobrevivência em casos graves, tratar ou prevenir metástases. Foram seleccionados pacientes que efectuaram cirurgia há pelo menos 3 meses e em plano de quimioterapia.

Objectivo: Avaliar a viabilidade de uma avaliação objectiva da influência do qigong na qualidade de vida e sintomas-chave da quimioterapia. Se assim for, estudos objectivos podem ser desenvolvidas para ver se os pacientes podem beneficiar com a terapia qigong em termos de prevenção de efeitos colaterais.

Notamos também que a mobilidade do ombro/braço se apresenta muitas vezes comprometida como consequência da cirurgia. Como tal, foi também avaliada.

Método: Os pacientes foram avaliados usando questionários para pacientes com cancro (QLQ-C30) e o módulo respectivo para cancro da mama (QLQ-Br23).

As escalas funcionais avaliadas foram o funcionamento (1)físico, (2)ocupacional, (3)emocional, (4)cognitivo e (5)social, assim como, (6)imagem corporal, (7)funcionamento sexual, (8)prazer sexual e (9) perspectivas futuras.

Além disso, o estado geral de saúde e possíveis dificuldades financeiras foram também avaliados.

Os sintomas avaliados foram (1)fadiga, (2)náuseas e vómitos, (3)dor, (4)dispneia, (5)insónia, (6)perda de apetite, (7)obstipação, (8)diarreia, (9)efeitos sistémicos da terapia, sintomas relacionados com a (10)mama e (11)braço e, (12)queda de cabelo.

Os níveis de cortisol salivar foram determinados como um parâmetro objectivo de stress. A incapacidade de movimento do ombro do lado afectado foi avaliada como referido anteriormente.

Os pacientes foram divididos em dois grupos: qigong (N^o=11) sujeito a quimioterapia e exercícios de qigong; Control (N^o=5) sujeito apenas a quimioterapia. A terapia de qigong foi feita 2 vezes por semana durante cinco semanas.

Critérios de inclusão: Idade > 18 anos, fisicamente apto para a prática de exercício físico, consentimento escrito, cirurgia há pelo menos 3 meses, tratamento quimioterapia.

Critérios de exclusão: Sofrer de doença psiquiátrica crítica, contra-indicação médica.

Resultados:

1. Em todos os scores dos itens/sub escalas funcionais e da qualidade de vida em geral verificou-se, no grupo de qigong, uma melhoria no desempenho como avaliado pelos questionários QLQ-C30 e QLQ-Br23.

As sub escalas de funcionamento cognitivo ($p=0,046$) e perspectivas futuras ($p=0,046$) melhoraram de forma estatisticamente significativa. No entanto, no grupo de control, todos os sintomas tendencialmente agravaram. Na sub escala de estado geral da saúde encontrou-se um agravamento estatisticamente significativo ($p=0,046$), um resultado que obviamente foi prevenido no grupo de qigong apesar de a quimioterapia também estar a ser aplicada.

2. Os sintomas tendencialmente melhoraram no grupo de qigong (não sendo estatisticamente significativo). Porém, no grupo de control todos os sintomas tendencialmente agravaram. Inclusivamente, a dor ($p=0,05$) e a perda de cabelo ($p=0,046$) agravaram de forma estatisticamente significativa.

3. Sintomas específicos como as náuseas e os vômitos apresentaram-se piores em ambos os grupos, no decurso da quimioterapia. No grupo de qigong não houve agravamento estatisticamente significativo. Porém no grupo de control, as náuseas e vômitos, mostraram um agravamento estatisticamente significativo ($p=0,035$).

4. Os níveis de cortisol salivar diminuíram em praticamente todos os pacientes do grupo de qigong e control, sendo esta diminuição mais significativa no de qigong (resultados sem evidência estatística).

5. Na avaliação da amplitude de movimento do ombro do lado da mama afectada, verificou-se que ambos os grupos apresentavam alterações na mobilidade e dor. Houve uma melhoria significativa no grupo de qigong ($p=0,008$), em comparação com o grupo de control.

Discussão

A funcionalidade e estado de saúde em geral melhoraram com o qigong. Foi seleccionado um sistema específico dos conhecidos exercícios *White Ball* desenvolvidos

pelo Instituto Heidelberg baseado no Modelo de Medicina Chinesa de Heidelberg. Estes exercícios podem ser utilizados neste contexto.

Contudo, tendo em conta a metodologia deste estudo, o principal problema em adaptar os grupos de control aos estudos de *qigong* mostra os limites da base do estudo convencional de *qigong*. Embora os resultados sejam promissores, é recomendado uma continuação do estudo com aumento do número de casos.

Palavras-chave: Cancro da mama, quimioterapia, qigong, Modelo de Medicina Tradicional Chinesa de Heidelberg, Qualidade de Vida

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ACRONYMS

AC – After Christ

AIDS – Acquired Immunodeficiency Syndrome

BC – Before Christ

CT – Chemotherapy

EAV – Electro Acupuncture according to Voll

EORTC – European Organization for Research and Treatment of Cancer

GDH – General Direction of Health

IPO – Institute Portuguese of Oncology

QLQ – Quality of Life Questionnaire

QoL – Quality of Life

Rs - Raw score

SPSS – Statistical Package for the Social Sciences

TCM – Traditional Chinese Medicine

US – United States

VC – Variation Coefficient

WHO – World Health Organization

WHOQoL – World Health Organization of Quality of Life

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INTRODUCTION

The aging population, resulting of a reduced mortality and increased life expectancy, is one of the greatest challenges that world must deal.

According to an estimate of the World Health Organization (WHO) in 2005, 22,1% of the world population had 60 years old or more.

As a result, the incidence of chronic diseases is also increasing: according to the report of Eurobarometer (2002), Portugal is one of the European countries with higher incidence of chronic diseases, is also the second European country with the highest percentage of individuals in long term treatment and where they have a worse opinion about their own health. Based on the report of Pain in Europe (2003), it is estimated that about 2 million people suffer from chronic pain in Portugal.

A chronic disease is a complex phenomenon, usually accompanied by a complex set of somatic and psychosocial factors, which damage the quality of life of those affected.

Amongst chronic diseases, we highlight the area of oncology. Indeed, cancer has become one of the major health problems of the 20th century. According to Miranda (1994), one in four people have had, have or might have to face this disease in Europe. In Portugal, it is already the second cause of death and one of the leading causes of disability.

Breast cancer is the prevalent malignancy in the industrialized world. In 2000, the International Agency for Research on Cancer estimated for Portugal the emergence of 4324 new cases of breast cancer and 1596 of those could be mortally associated. Considered a treatable and curable disease, breast cancer and its inherent process (diagnosis, treatment and clinical assessment) may lead to different physical and psychological consequences. It takes us to a complex matter: consider all aspects related to quality of life and patient's adjustment through the course of disease.

According to WHO, the concept of quality of life is translated as "self perception of their position in life within the context of systems of culture and values on which it is inserted and in relation to its objectives, expectations, standards and concerns" (WHOQOL-Group, 1994).

The definition quoted above shows the subjective and multifactorial nature of cancer. The concept of quality of life and so the way to deal with cancer is also unique, personal and specific to each patient.

Given the different possibilities of patient's reaction to a diagnose of breast cancer, it's important to identify specific rehabilitation needs, whether they are physical, psychological, social, sexual, or other, in order to understand the impact of the disease.

Over the years, there have been various ways to cope and deal with situations of oncological being, increasingly being moved towards to a perspective of integrative medicine. This term refers to treatments approaches that combine conventional medicine and complementary modalities. It is important for patients to have at their disposal multidisciplinary team acting in different ways and perspectives, so they can have an integrated view of the patient as a whole. Some studies have confirmed the effectiveness of a multidisciplinary treatment of oncological diseases; it seems that combining treatments is more successful than the proposed one-dimensional treatment. For instance, Graner (2010) considered that, complementary and alternative therapies aim to reduce symptoms and promote quality of life in different stages of treatment concomitantly to clinical usual.

In this context, arises the importance of *Qigong*. *Qigong* is a term used for various exercises and therapies as part of Traditional Chinese Medicine (TCM). It is considered a process of self-training through which physical and mental health are cultivated and fighting disease. Same studies (Chen, 2002) have been proving its effectiveness in health promotion and disease prevention, particularly regarding quality of life of patients with cancer. In fact, health promotion and disease prevention have been the basis for life conditions improvement.

This study focuses on the importance of regular practice of *Qigong* in quality of life of those patients. The theme chosen has the purpose to respond to strategic orientations of the National Health Plan 2004-2010 (*Plano Nacional de Saúde 2004-2010*), which advocates more and better investigation for health, especially for chronic diseases and/or diseases causing incapability. Amongst them is breast cancer. The chosen problematic was based on real cases of women who needed some sort of alternative therapies while doing the regular treatment. Furthermore, as a health professional and woman, I'm aware of the devastation caused by breast cancer and I'm willing to find potential solutions for problems and needs of this particular group.

This work emerges from a constant deeply scientific questioning. It's divided in two parts, which are divided in chapters. The first part contextualizes the problem, which presents a literature on the subject since its concept, physiological, psychosocial and energetic approach and the practice of Qigong in particular; the second part presents the methodological framework and research results.

PART I

THEORETICAL FRAMEWORK

1 – ONCOLOGICAL DISEASE

1.1. – Comprehension of the phenomenon

Chronic diseases represent a complex phenomenon, defined as an individual and subjective event. Throughout the literary research, most definitions present several factors, including physical, psychological, emotional, social and cultural as intervenient in each dimension of this phenomenon. According to Carvalho (1999), patients with chronic diseases often present co-morbidity, in which there's a high prevalence of depression, anxiety, sleep disorders, isolation and interpersonal relationships problems. Therefore, it is a relation between sensory, cognitive and affective components. The emotional component involved in chronic diseases is as important as the sensitive component itself.

Cancer is one of the most common chronic diseases and is currently considered one of the main health problems of the twentieth century. Indeed, the extension of life of patients with cancer has increased and "cancer came to be regarded as a chronic disease with periods of remission and relapse" (Sá, 2003, p.23). In recent years, an increasing awareness of interpersonal and emotional repercussions of cancer and its treatments has happened, as well as its impact on the welfare of patients. Thus, the attention has been directed also to the psychosocial needs of patients, their families and health professionals and to the impact of emotional and behavioural factors at the beginning and during the course of the disease.

At this stage of life, the quality and quantity of support received is important during the whole process and development of disease. Santos (2003), in an adaptation study of the satisfaction scale with social support to people with cancer illness diagnosis found that, the satisfaction with the social support relates to the all adaptation process to oncologic disease and results, specifically concerning to quality of life. Based on the WHO definition of health as "a state of complete physical, mental and social welfare and not merely the absence of disease", it becomes essential to see the patient as a whole, recognizing its needs in several aspects. The ongoing research in such an important area as cancer is undoubtedly essential. More and more is known about its causes, risk factors and development. New ways to prevent, detect and treat are also being studied always focusing on improve the quality of life of patients with cancer.

The concern about the quality of life of cancer patients has undoubtedly increased - the studies on cancer tend to be a quarter of all studies on quality of life (Ribeiro, 2001). The concept of quality of life can be interpreted from person to person differently,

according to their own perspective, described as subjective judgments of satisfaction or a sense of personal well-being, combining biomedical, psychological, behavioural and social indicators (WHO, 1994).

Over the years, scientific literature has revealed some difficulty on the concept's definition, which must be understood within a cultural and social environment of individuals and contexts of intervention. The quality of life assessment of individuals suffering from chronic disease may represent a very important area in providing care, treatment compliance and satisfaction, revealing its great importance in the evaluation of health care. Thus, it is not only to quantify the presence or severity of disease's symptoms, but also to demonstrate how the manifestations of a disease or its treatment are experienced and perceived by each individual.

The cancer is reported in the medical papyri from the Egyptians and Persians (3500 BC), however is in the writings of Hippocrates where it was first detected the definition of cancer, such as "carcinoma" or "cirrus" (Dias & Miranda, 1993). In fact, human beings have had cancer throughout the history; it is not a surprise that people have written about cancer in previous times. As mentioned above, some of the earliest evidences of cancer were found among fossilized bone tumours, human mummies in ancient Egypt and even in ancient manuscripts. Bone remains of mummies have revealed growths suggestive of the bone cancer. The Universal Dictionary of the Portuguese Language (1995) defines cancer as "a disease caused by an uncontrolled reproduction of malignant cells, which are independent of any control by the body, ultimately invade tissues and organs and cause organic changes; cirrus, cancer, venereal ulcer origin; evil that will gradually ruining".

Nowadays, most cancers are treatable and cured. Nevertheless, the persistent fears inherent to the diagnosis of this disease continue. The treatments can last for very long time and it could become impossible for the patient to be professionally active during the period of the disease, which leads to an uncertainty about the future. Indeed, chronic pathology, particularly in oncology, it is usually accompanied by a complex set of somatic and psychosocial factors that are an integral part of the whole problem and may intensify the patient's suffering. Moreover, the effects of chronic disability as well as the effects on family, regarding social and financial level inherent to this, contribute to prolonged suffering and may sometimes interfere with patient's rehab.

Despite the increasing efficiency of methods embodied in more lasting survivals, patients face a potentially debilitating disease, pain, change in physical self-image and loss of physiological functions.

According to King(2) (1998), the reaction that each one has to a malignant disease is influenced not only by the disease itself, but also by psychological, social, familiar and spiritual factors. This affects quality of life, but not constantly the same way. The response of each individual will also depend on his life cycle stage. Ogden, quoted by Ribeiro (1998), refers that more than 20% of cancer patients manifested severe depression, grief, loss of control, personality changes, anger and anxiety.

It is not possible to explain clearly and objectively why does a person develop cancer and another doesn't. However, studies show that certain risk factors increase the potentiality of a person to develop cancer. Some can be avoided, others not. Amongst them are aging, smoking, radiation, viruses and bacteria, hormones, diet, physical inactivity, family history, and others.

The treatment plan depends essentially on the stage the disease is and type of treatment to be made. In some cases, the primary objective is to heal other controlled disease and reduce symptoms.

1.2. – Breast cancer

1.2.1. – Definition

The female breast is a very complex glandular organ and the site of the most commonly occurring cancer in women.

As mentioned before, the term “carcinoma” is used to describe a malignant or cancerous growth. In fact, breast cancer begins when cells of the breast suffer changes, where a normal cell converts into a cell that has an uncontrolled growth pattern. When those cancer cells continue to divide, grow and spread to other parts of the breast or even to the body are called metastasis. The breast is composed of fat tissue, nerves, veins, arteries, connective tissue, muscle, lobules and ducts (Figure 1). The lobules produce milk that is transported by channels, called ducts, to the nipple during breastfeeding (Kneece, 2005).

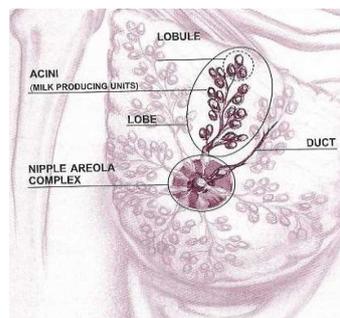


Figure 1 - Breast constitution (Kneece, 2005)

There are different types of breast cancer according to the different tissue or part of the breast affected, and may have varying characteristics. They are named according to the part of the breast in which they develop. On one hand, those who begin in the ducts are called *ductal* carcinomas and, on the other hand, those who begin in the lobules are called *lobular* carcinomas.

1.2.2. – Prognosis and costs

Breast cancer is the most common malignant disease worldwide. According to the National Cancer Institute, the U.S. estimated for 2010 the emergence of 207,090 women and 1970 men new cases of breast cancer, and 39,840 women and 390 men of those will be cases of death.

In 2004, data from the report of General Directorate of Health (DGS, 2004) titled: “The risk of dying in Portugal”, showed that there were 1443 deaths from breast cancer, registering a higher number of deaths in the region of Lisbon and Tagus Valley (582 deaths), followed by the North (323 deaths) and Central region (319 deaths). The mortality was lower in other regions: Alentejo (67 deaths), Algarve (59 deaths), Azores (43 deaths) and Madeira (46 deaths) (DGS, 2004). Nowadays, cancer is the second leading cause of death in Portugal, after cardiovascular disease, and its high percentage in total of deaths reveals a steady increase and progression (Araújo, 2009). According to the National Statistics Institute, mortality caused by cancer in Portugal stabilized at 2,1% per thousand inhabitants. According to the same author, 4,7% of total medical costs were because of cancer, and direct medical costs, about 69,4 billion dollars, in the U.S., in 2004.

According to the cancer registry of the Portuguese Institute of oncology of Porto, in 2009, breast cancer represented 18,8% of all carcinomas registered in the referred institution.

The following table shows some data of the cost of cancer treatment, in which we can see the direct cost of cancer treatment in Portugal that represents 3,91% of total health expenses and that represents about 53€ *per capita*.

	Direct cost of cancer (million €)	Direct cost of cancer <i>Per capita</i>	Cost of cancer in %, regarding health costs	Total health Costs (million €)	Population (2007)
Portugal	565,03 *	53,33	3,91	14500 **	10595600

Table 1 - Costs of cancer treatment in Portugal (Araújo, 2009)

*results of 2006 related to hospital admission, chemotherapy, radiotherapy and drugs

**results of 2005

The following data represent the sum of oncological costs in chemotherapy, radiotherapy, drugs and medical consultations, referenced by the GDH in 2006.

Price of oncologic DRG (2006)	313.792,774 €
Chemotherapy costs (patient admitted) (2006)	17.365,170 €
Radiotherapy costs (2006)	75.034,009 €
Price of chemotherapy (daily) (2006)	125.882,086 €
Medical consultations	29.460,463 €
Costs of oncologic drugs	3.500,000 €
Total	565.034,503 €
% (regarding total health costs)	3,91%

Table 2 - Costs of different types of cancer treatment in Portugal (Araújo, 2009)

According to a North American study of cancer, this is the world's most expensive disease, regarding number of deaths and lost productivity associated to it (Public, 2010). The same study shows the fact that cancer has a bigger impact in productivity and loss of human lives than AIDS, paludism, flu or other contagious diseases. Based on the reports of WHO and economic data from the World Bank, scientists have concluded that cancer has an economic impact of 895 billion U.S. dollars, surpassing the 753 million of costs related to heart diseases (Public, 2010).

The above shown numbers, concerning incidence, mortality and survival, pose a great challenge. On one hand, if there are more survivors with cancer, firstly we need to understand the factors that play an important role in its development and its evolution and, on the other hand, understand the impact of the diagnosis and treatment of cancer, as well as designing an intervention in order to regain and maintain QoL.

1.2.3. – Etiology and Pathophysiology

The breast cancer has been associated to negative beliefs and women with breast cancer are targeted for what is called double-stigmatized. Firstly, the diagnosis of the disease initiates a process of social withdrawal and difficulties to deal with the situation and, secondly, by blaming the victim when diagnosis of cancer is associated to the absence of a preventive attitude. It's considered one of the diseases causing major impact on society, not only because it's very often, as mentioned before, but also because it strikes an organ and its symbolism, maternity and femininity.

The factors responsible for the onset of breast cancer are not yet fully defined. Different factors are well documented as being at risk. However, only a small percentage

of women diagnosed with breast cancer have shown some of these factors (Patrão, 2007).

Early detection seems to be one of the most important forms to control breast cancer. According to Crane (2000), the regular practice of breast self-examination could reduce mortality from breast cancer by approximately 19%.

The risk factors generally considered in literature are:

- Hormonal (prolonged exposure to estrogen by: early menarche, late pregnancy, multiparity, late menopause, overweight after menopause, using of oral contraceptives, hormonal replacement therapy);
- Related to lifestyle (diet with a high content of fat, obesity, consumption of alcohol and tobacco)
- Age related (incidence of breast cancer increases with age)
- Related to the presence of benign breast disease and a family history of breast cancer
- Related to the influences of radiation
- Related to genetic susceptibility
- Related to psychosocial factors involved in the development and progression of breast cancer, working likely through the hormonal and immune system.

(Patrão, 2007).

Although most associated factors in the prognosis of breast cancer are physical, such as the physiological characteristics of the tumour size, presence or absence of metastasis, among others, the psychosocial aspects also have a significant impact on prognosis. Grossarth-Maticek (1999) refers that psychological factors interact with physical ones, and this interaction is not only additive but synergistic. Feelings such as depression, anxiety and aggression are constant in women diagnosed with breast cancer. Indeed the diagnosis of breast cancer has, in most cases, a significant impact on psychosocial functioning of patients and their QoL, particularly regarding their psychological adjustment, emotional well-being, social, body image, sexuality and physical condition (Moreira, 2008). According to the same author, the fear of death, uncertainty about the future, the loss of autonomy, fear of pain and suffering are common conditions in this type of patients that may arise in the initial stage of the disease and extend beyond the end of treatments.

Almost 2000 years ago, Galen noted in his book *De Tumoribus* that melancholic women were much more susceptible to cancer than other females, and similar involvement of psychological factors was noted in the medical literature of the last three centuries (Grossarth-Maticek, 1999). Burgess et al (2005) found in a sample of 222 women with breast cancer, approximately 33% of these women had clinically significant

levels of depression and anxiety. Accordingly to this author, it seems that cancer is more likely in people who suppress their emotions and self-regarding instincts, appearing bland and exaggeratedly helpful and altruistic, that cannot cope with stress, develop feelings of hopelessness and finally depression. Moreover, cancer is often associated with pessimistic thoughts that frequently diminish the individual and others.

In the 60`s, there was the emergence of the cognitive theory that it is known that the mere fact of repeating negative statements can maintain a depression.

According to Canavarro (2008), a research about this area, particularly as regards the assessment of QoL and psychosocial adjustments of survivors with breast cancer, show that, in general, the quality of life is good, although the results are worse in the physical domain resulting of emergence or persistence of symptoms such pain, loss of sensation, oedema and changes in the mobility of the affected arm, among others.

1.2.4. - Clinical staging

The clinical staging is to assess the extent of disease in the origin's organ and its extension to adjacent organs or structures and as well as to surrounding and distant lymph nodes. Although there are several systems for staging solid tumours, the most widely used and universally accepted is the TNM – Classification of malignant tumours, of the International Union against Cancer. This is also the most widely used classification system in Portugal. The main objective is to have accordance with the international classification of cancers based on the extent of disease, enabling better communication.

According to TNM, this system is supplemented with information obtained through some means of diagnosis. The classification describes the anatomical extent of disease based on assessing 3 components:

T – The extent and location of primary tumour

N – Absence or presence and extent of metastasis to surrounding lymph nodes

M – The absence or presence of distant metastasis

(International Union against Cancer, 2006)

The most frequent sites of metastasis of breast cancer are bones, lungs, pleura, liver and the adrenals (Crane, 2000).

1.2.5. – Conventional treatment approach

The therapeutic approach to breast cancer involves, in most cases, surgery, chemotherapy, radiotherapy and hormone therapy. Typically, the recommended treatments combine two or more approaches, according to individual characteristics, both

psychological and clinics in order to guarantee a better quality of life after treatment. There is no doubt that the type of treatment will have an impact, not only on longevity, but also on quality of life, so this variable has indeed to be compelling both in the selection of treatments and afterwards in the results' evaluation.

Cancer treatment has gone through a slow process of development. It was in the 19th and early 20th centuries that major advances were made in general surgery and cancer surgery. During the final decades of the 20th century, surgeons developed greater technical expertise in minimizing the amounts of normal tissue removed during cancer operations. This progress depends not only on understanding cancer better as a disease and on better surgical instruments, but also on combining surgery with other kinds of treatments such as chemotherapy and radiation.

Usually, surgery is one of the first treatments, except when there is need for another type of treatment as an adjuvant. The type of surgical procedure (which may be more conservative or more radical) depend on the size of the tumour, the history of the patient, breast size, shape and preference of the patient (Crane, 2000).

Another 19th century discovery laid the groundwork for an important modern method to treat and prevent breast cancer was the hormone therapy. According to the American Society of clinical oncology (2009), Thomas Beatson, graduated from the University of Edinburgh in 1874, developed an interest in the relation of the ovaries to milk formation in the breasts. He discovered the rabbits' breast stopped producing milk after removal of the ovaries. He has discovered the stimulating effect of the female ovarian hormone (estrogen) on breast cancer, even before the hormone itself was discovered. His work provided a foundation for the modern use of hormone therapy to treat and prevent breast cancer.

Radiotherapy is another treatment commonly used against cancer. Radiation therapy began with radium and with relatively low-voltage diagnostic machines. Methods and machines for delivery of radiation therapy have steadily improved. Nowadays, radiation is delivered with great precision to destroy malignant tumours and controlling damage to nearby normal tissues (American Society of Clinical Oncology, 2009).

Finally, chemotherapy is one of the most used treatments against cancer and it's through drugs administration. Indeed, over the years, the development and use of chemotherapy have resulted in the successful treatment of many people with cancer. Nowadays, several approaches are being studied to improve the activity and reduce the side effects of chemotherapy. According to the American Society of clinical oncology (2009), these include:

*New drugs, new combinations of drugs and new delivery techniques;

*New approaches to targeting drugs more specifically towards cancer cells in order to produce fewer side effects;

*Drugs to reduce side effects like anti-emetics and chemo protective agents;

*Agents that overcome multi-drug-resistance.

Usually, each chemotherapy protocol consists on using a single cytostatic or combination of 2 or more different cytostatics, as tumour cells are able to easily mutate and develop resistance to them. Depending on the objectives to be achieved, there are several types / objectives of chemotherapy treatment:

* Neo adjuvant chemotherapy – used in larger tumours, before surgery, to facilitate conservation after breast surgery;

* Adjuvant chemotherapy – used after surgery for removal of waste excised during surgery and the eradication of small metastasis;

*Second line and palliative chemotherapy – in case of relapse, controlling symptoms and improving quality of life (Dooms, 2006).

Given that the most of breast cancer treatments also damage healthy cells and tissues, there are physical side effects associated to it. They depend mostly on type of treatment, and its extension, but can vary from person to person and even for the same person at different treatment sessions. After analyse each specific situation, it must be considered the quality of life before current illness of the patient and the one that can be expected during treatment. Therefore, according to Bech (1993), assessment of quality of life about cancer was added as a fundamental dimension in clinical trials. Nevertheless, according to a study conducted by Sá (2003), it seems that association between chemotherapy and radiotherapy, despite the increased number of survivals, was negatively associated to quality of life. Also Kiebert and his colleagues (1991) found that a more conservative treatment of breast cancer seems to show beneficial impact on quality of life.

As stated before, all of these treatments have side effects. Side effects of a mastectomy, associated to physical problems caused not only by the surgery, but also by axillary dissection, frequently cause psychological changes as it was already described. Patients must be prepared to face their alterations of self-image resulting by a mastectomy. Among the most frequent physical changes are pain in the affected site, decreased strength and mobility on the affected arm and oedema (National Cancer Institute, 2011).

In fact, pain is considered the 5th vital sign, therefore, General Directorate of Health (2003) assumes that control of pain must be like a duty for health professionals, is a patient's right not to suffer with it and is a major step to humanize care units. Also the so

called *Frozen Shoulder*, that causes a muscle and joints atrophy, needs specific physical exercises.

Regarding chemotherapy treatments, as cytostatic drugs don't distinguish tumour cells from normal cells, it could appear symptoms such as:

- *Alopecia – although reversible and not endanger to patients' lives, is seen as one of the most stressful secondary effects (Holland, 1989), interfering with patient's body image;

- *Gastrointestinal system symptoms – anorexia, nausea, vomiting, mucositis, stomatitis, diarrhoea, taste changes, smell of food aversion;

- *Hemorrhagic cystitis

- *Neuropathies

- *Skin colour changes

- *Decreased libido

- *Fatigue, tiredness

(National Cancer Institute, 2011)

Side effects associated to radiation therapy are usually mild and reversible, and include local changes in skin, fatigue, pain related to temporarily inflammation of the nerves or muscles in radiation domain (National Cancer Institute, 2011).

Hormone therapy has few side effects; those include mild malaise, nausea and menstrual cycle changes (National Cancer Institute, 2011).

1.3 – Novel approach in cancer

A variety of modalities can be used to improve breast cancer patients' quality of life. A combination of those modalities of pharmacological and non pharmacological treatment of cancer is a mainstay of supportive care to those patients as presented on the current WHO guidelines.

The study and interest in learning/understanding treatment modalities called complementary or integrative medicine has grown significantly in recent years. A study conducted by Eisenberg et al (Lima, 2009) revealed that one in three respondents had used non conventional treatment modalities. The complementary term or integrative medicine is here mentioned, referring to treatments that combine conventional medicine with complementary modalities. Highlights, the importance of therapeutic relationships between doctor and patient, focus on the whole person, including all aspects of life. The central focus is the patient's perspective, generating new strategies and multiplying treatment possibilities. According to Cassileth (2004), cancer patients usually use complementary therapies, being that about 91% of these patients used some form of

complementary therapy during conventional medical treatment, in the United States. Although some are expecting these therapies to have an effect on their survival time, it seems that most use these methods to improve quality of life (Cassileth, 2004).

Indeed, in recent decades, there is a growing consensus regarding the evaluation of the effectiveness of therapeutic interventions not only regarding quantity of life (survival rate) but, also quality of life. When talking about cancer disease, it seems fundamental to speak of quality of life, since not always the survival rate is high, which makes other aspects of patient's life so or more important. On the other hand, the assessment of quality of life provides significant clinical information to support certain clinical decisions and choice of more appropriate treatment.

One of the so called complementary therapies is the Traditional Chinese Medicine that it will discuss bellow.

2 - TRADITIONAL CHINESE MEDICINE

2.1. - History

Since the origin of time, men try to fight pain and disease true different methods and means. Traditional Chinese Medicine is one of them, born in China over 5000 thousand years ago.

The oldest findings known, where references to the most primary forms of care are shown, are the *I Ging* (The book of changes) and the *Huangdi Neijing* (Principles of Interne Medicine of the Yellow Emperor). It is thought that the book *Huangdi Neijing* was written somewhere in between the 2th century BC and the 2th century AC and establish, for the first time on the Chinese Medicine practice, some of therapeutic principles of treatment. There, it's described the most important channels, the different needles that were used, some of the application techniques of those needles and also the use of some acupuncture points. Related to the preservation of a healthy energy in human beings, it's described in *Huangdi Neijing* that "*Those who in ancient times known the way to preserve a good health, always guide they behaviour accordingly to nature. They follow the yin and yang principle and preserve accordingly with the prophecy art, based on the yin and yang interaction. They were capable of changing their daily life in harmony, so they can recovered the essence and vital force, preserving a good state of health. Their behaviours of everyday life were all kept in regular patterns such as its food and drink, kept in fixed quantity, and daily activities at regular intervals. Never exceed at work. That way they could keep in both body and spirit the substantial, and were able to live until a ripe old age of over one hundred years*" (2001, p.25).

Over the centuries, many compilations and reassessments of the whole field of knowledge of Chinese Medicine appeared. However, it was on the 16th and 17th centuries that the preservation and dissemination of this whole field of knowledge reached its pinnacle, with publications such as *Zhengjiu Dacheng* (Great Compendium of Acupuncture and Moxibustion). In it was the theory behind all Chinese Medicine, such as stimulation of points and channels, which have been presented so clearly that remain current until present day.

Accordingly to Hemen (2006), it was Soulie de Morant, at France, after 30 years of study in China that contributed, in a fundamental way, to provide the theoretical basis for the diagnosis and the introduction of Chinese Medicine in the western world. Indeed, in

the 1920s, translations of Soulie de Morant were of great importance. The book *L'Acupuncture Chinoise*, published in 1939, allowed a great dissemination of acupuncture in France.

In the 1960s, it was developed an interest in acupuncture in other countries such as Japan, where acupuncture was practiced alongside with China. It has become more popular in the United States after 1971, with the article written by the journalist James Reston in New York Times. This journalist, when accompanied the President Nixon on his trip to China, developed appendicitis and it was applied acupuncture to relieve his pain after surgery (Ferreira, 2010). Research in the area of TCM has had a great impulse in the 1970s, after the description of endorphins; through this it was found one of the reasons to justify the analgesic effect of acupuncture. By this time, also in Portugal these techniques were developing in clinical field more intensively.

WHO meet the needs of promoting safety, quality and effectiveness of traditional medicines, issued the "WHO Traditional Medicine Strategy: 2002-2005", urging governments to establish appropriate policies and practical training in those areas. In the document "Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine", of January 2004, WHO concludes that effectiveness and benefits of so-called Traditional Medicines depends on an adequate education and training, skills and a quality service to provide their population. Currently, there is a form of modern understanding of TCM considered crucial for their integration into the Western health system and in research. The Heidelberg model fits in this context.

2.2. – Definition

Western medicine, as well as any other type of *corpus medicus*, presents limitations both in diagnosis as in interventions. Indeed, for a long time, Western medicine has been systematically built and developed based on scientific methodology and, as a result, on the possibility of the phenomena being measured. In this perspective, the findings of targets, measured by equipment overlap empirical data provided by patients.

It is estimated that about two thirds of the population does not feel healthy, suffer from any kind of pain, discomfort, hypersensitivity, among other situations. Ferreira referred for example, that "low back pain is a frequent cause of morbidity and disability overlapped only in painful disorders that affect people by headache. However, in a primary approach, only 15% of back pain has a specific cause" (2009, p.64). Indeed, only to a minority of people it's possible to establish measurable cause for their symptoms and, therefore, impossible to establish a diagnosis according to western medicine. Another limitation of western medicine refers to patients suffering from chronic diseases. They may

have a medical diagnosis clearly identified but often western medicine offers only symptomatic relief of symptoms and not cure, for example in patients with asthma, diabetes mellitus, among others. These are some of the reasons why, according to WHO, about 70-80% of the population in developed countries used some form of alternative or complementary medicine (WHO, 2009).

Chinese Medicine emerges as another medical approach, considering the human being part of a whole, being interested primarily in the expression of life, emotions and vital body functions in order to identify possible disharmony. As stated above, a current understanding of TCM considers it as system of biological model with the aim of a holistic treatment of the condition of disease. The basic aim is not to measure or assess a specific organic change but to evaluate the condition of a patient, reporting objective and subjective their symptoms or discomforts.

2.3. - The Heidelberg model of Chinese Medicine

MTC is understood as a system of feelings and findings designated to evaluate the vegetative functional state of a person (Greten, 2008). Accordingly to the Heidelberg model, it consists on a rational science with medical diagnosis, based on symptoms that constitute the reality of the current evidence of disease and pathological changes. It is supported by a system that describes functional abnormalities through its signs and symptoms. Thus, it is understood that those signs and symptoms, as well as the feeling that the patient describes, are the result of dysfunctions in the body, particularly in the neurovegetative system. The data collected indicate possible diseases, resulting in a disharmony of one or more of these functional systems. As a scientific medical diagnosis, besides the interpretation of symptoms, amounts to a second level of abstraction, which identifies causes and agents that can induced those changes or dysfunctions (Greten, 2008).

This referred state can be treated in various forms. The therapy includes therefore reflex action at central and vegetative nervous system such as acupuncture and manual therapy (Tuina), as well as exercises that activate the vegetative system of biofeedback, the Qigong. Herbal and dietetic are also included as an effective therapy through the administration of plants, minerals and other products, but also through the food itself.

Hempen (2006) reported that, for the TCM be considered scientific, it must respect and fulfil some scientific criteria. Therefore, it should be based on extensive clinical experience, use a specific language and terminology in order to express their views and yet, the author refers that, to clinical observations of Chinese Medicine and acupuncture

become a body of scientific knowledge, it must be integrated into a rational system of systematization of concepts.

In order to understand the mechanism of action and pathologic processes in general, from a TCM point of view, there must be a number of basic concepts to be understood. The concept of *Qi* is frequently translated as “energy” or “vital force”. According to Porkert (1995), it refers to an immaterial energy with a qualification and a direction. According to the Heidelberg model, *Qi* can be understood as a vegetative ability of a tissue or organ that cause in it different sensations and findings (Greten, 2008). The concept of *Qi* is at the core of TCM and assimilate the concept is the conceptual lead required to understand it. It’s described in TCM different types of *qi* according to their qualification. On this context, it seems relevant to distinguish the nutritive *qi* and the defensive *qi*, which, accordingly to the Heidelberg model of TCM, are the more implicated in the process of development of cancer (Greten, 2009). The defensive *qi* is located on the outside of conduits, within the tissue and their free distribution for the body is believed to be dependent on the influence of the pulmonary orb (described later); on the other hand, the nutritive *qi* is originated from the ingested food (Greten, 2008).

The conduits above cited, are considered to be the result of the connection of a group of points with effect on a particular set of clinical signs, believed to be responsible for the free movement of *Qi* (Greten, 2008).

In order to understand the phenomenon of pathogenesis, from a TCM point of view, it’s important to decode it to some other underlying concepts. Accordingly to this model, the term “phase” is referred to a vegetative tendency, i.e. the higher trend, the more likely occurrence of signs. To those signs, manifestations of the “phase” is called “orb”. “Orb” is a concept that describes the clinical manifestations of a “phase”, which manifests itself in a particular body region which, in turn, is also related with functional properties of their respective conduit (Greten, 2008).

In this context, according to the Heidelberg model of TCM, there are four major mechanisms that can cause disease/deregulation. One of them is the transition problem from one “phase” to another, which will cause blockade; excess of an agent (pathogenic factor that illicit a specific group of signs and symptoms); disharmony between antagonists which means a coordinated system failure of the “phases” and, finally, *yin* deficiency. *Yin* deficiency refers to a term that describes a structural deficiency condition. This lack of substrate causes an instable regulation in the patient (Greten, 2008).

This model of Heidelberg provides an overview of some words by translating them as states of neurovegetative functions, being crucial to the integration of TCM in the Middle West, particularly to what regards the health system.

On the following picture it is possible to make a western physiological description of such neurovegetative functions (Figure 2).

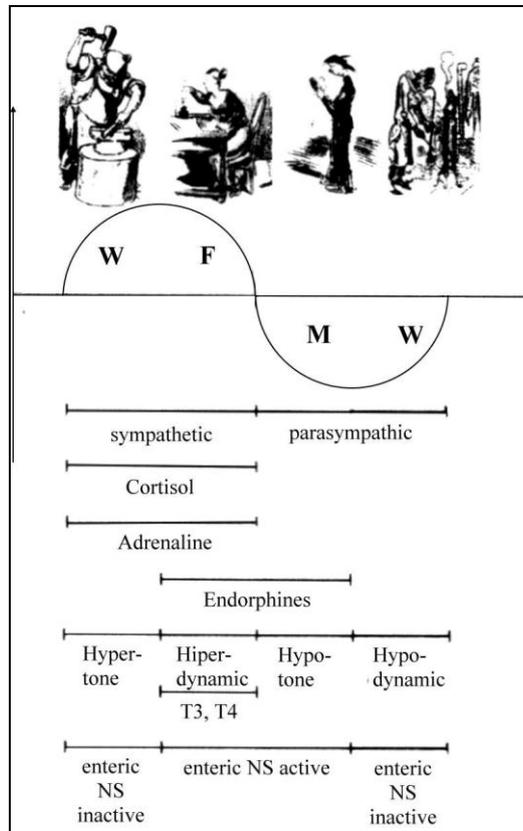


Figure 2 - Western physiological description of a vegetative sinus wave (Greten, 2008)

The sinus wave represents a sinus curve of regulation, a circular movement, as the classic circle of Yin/Yang, were are described the regulatory model of the phases (Wood, Fire, Metal and Water).

In the superior part of the figure, functional figures symbolize the clinical appearance of the mechanisms in terms of visible signs, that western medicine describe as transmitters and neural concert of the vegetative system (Greten, 2008).

For example, according to Greten (2008), stress is believed to be accompanied by a strong uprising sympathetic action, analogous to Wood. At the same time, according to western medicine, vagal impulses act to counter-balance this sympathetic action and effect. In Chinese terms this is as imbalance of a vegetative functional tendency. The functional tendency, called Wood, is more or less analogous to stress and sympathetic action, adrenaline increase, muscle tension, and others. To establish a diagnosis according to this model, in a first step it is defined the actual symptoms by terms of constitution, agent and orb.

The constitution is the overall of the individual functional properties and the inner nature of the patient, while agent is regarded as a functional power that may change the individual functional properties; it produces clinical signs or induce a group of diagnostically relevant signs called *orb* (Greten, 2008). In a second step, the symptoms are interpreted on the background of overall body regulation by means of guiding criteria as described following (Figure 3).

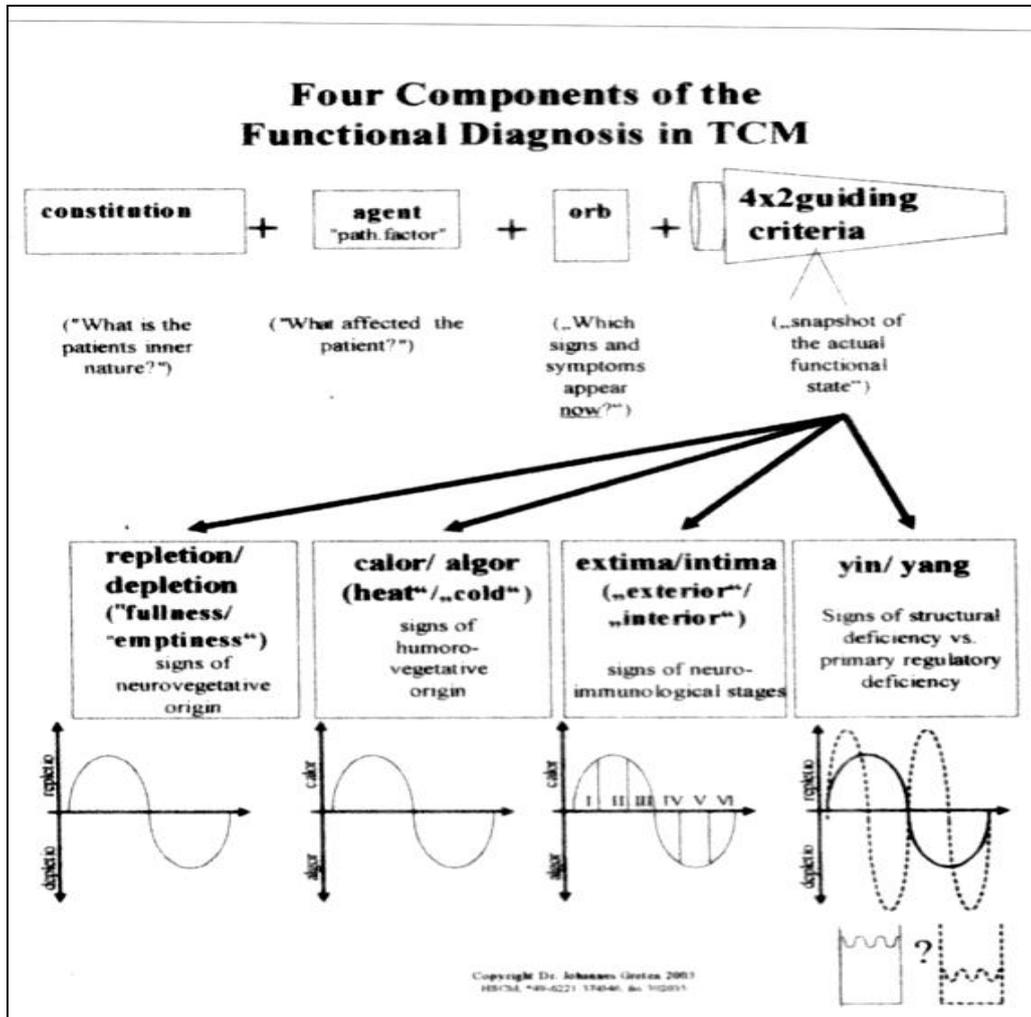


Figure 3 - Four components of the functional diagnosis in TCM (Greten, 2008)

According to Greten (2008), a guiding criteria is an evaluation of clinical signs according to an underlying regulatory model of physiology.

2.4. – Cancer according to the Heidelberg model of TCM

Cancer, accordingly to the Heidelberg model, is understood in a comprehensive manner, as the result of a disharmony between *qi* defensive and *qi* nutritive, covered above.

In a very general way, what happens is that the referred disharmony causes, over time, a *qi* and blood (*xue*) stagnation, which can lead to blockage states and accumulations. According to TCM, cancer is the result of an excessive effect of *qi* nutritive that can cause blockages and stagnations (Greten, 2009). The cause of it should always be diagnosed individually.

Specifically, by local findings, this stagnation may result in three principal stages/situations of the disease:

*Stage I – accumulation of *humour* and *pituita* (similar to oedema) that causes or makes the conduits obstruction becomes worse.

*Stage II – Named *congelatio*, situation in which an excess of a palpable substance still moves in the tissues, it can resemble a situation of existence of cysts or chronic exudates.

*Stage III – Named *concretio*, situation of a local accumulation that is not mobile; treated as benign or malignant, situations such as lipomas, fibromas or other neoplastic conditions.

(Greten, 2009)

The concept here involved is that the defensive *qi* tend to disperse the accumulation of constructive *qi* and, when this process fails, pathological situations arise (Greten, 2009). A similar view in western medicine is that cancer is the result of an imbalance between the formation of new tumour cells and their destruction by the immune system. As a result, this imbalance between the constructive and defensive *qi* is always a potential situation for developing a tumour. The orbs mainly involved in this process are the pulmonary and the hepatic orb, being that defensive *qi* has more relation with the first and nutritive *qi* with the second. Thus, the appearance of a tumour can also be seen as an imbalance between those orbs.

At the level of emotions, the pulmonary orb has a relation to feelings of sadness and melancholy, as well as symbiotic relationship of dependency. On the other hand, the hepatic orb relates to states of anger, rage, as well as relations of independency and autonomy.

Discuss emotions and cancer, is discussing an imbalance between *maeror* and *ira* or symbiosis *versus* autonomy (Greten, 2009). Similarly, according to the western theory, cancer can be induced from life significant events that lead to emotional significant disturbances. According to this model, Hilakivi et al (1993) refer that there are three main hypotheses relating psychosocial factors in the etiology of cancer. First, the cancer may be preceded by significant stressful life events, particularly those that exceed an individual's ability to cope and manage them. Second, the psychological well-being appears to increase survival in those patients, and, third, a type of personality was

identified as being prone to breast cancer characterized by being “too much kindness” and inability to express emotions and cope with stress, as well as the need to have significant and satisfactorily relationships with others. Significant life factors are related to events, such as loss of an important relationship, personal injuries, changes in family members and marital problems. Stressful experiences in childhood and certain parental relationships were also described as being prone to later development of cancer. These relationships include loss or separation from a parent, a non loving mother or even an authoritarian father (Hilakivi et al, 1993).

Another study conducted by Cooper et al (1989), where they examined the experiences of stressful life events, considered in patients from two cancer centres, found that the incidence of those events was lower in both groups of women with breast cancer and cysts but, their perception of the severity of them was increased as compared to other groups of women without pathology. These authors interpreted that the greater the perception of an impact of a stressful life event is, the greater is the risk to develop breast cancer.

In the National Cancer Institute in Washington, the laboratory of Dr. Ron Herberman, analyzed a type of cell, the natural killer cells, in women newly operated to breast cancer. They showed that the more these cells were active in the following weeks after surgery, the greater the hope for survival of those women is. According to these researchers, women with breast cancer, capable to better deal with disease from a psychological standpoint, have many more Natural Killer cells active than those who are victims of depression and apathy (Schreiber, 2008). According to previously published studies, it seems that the crucial factors in tumour development is not exactly just the presence of stressors or not, but it seems to be more important the interaction between those factors, as also the personality and psychosocial support that lead to the ability or not of an individual to deal with all disease process.

2.4.1. - Breast cancer according to the Heidelberg model of TCM

The mammary glands, and consequently the breast cancer genesis, from a TCM point a view, have different conduit and orb relations. The orbs and their relation with the genesis of breast cancer that are explained bellow are accordingly the Heidelberg model of TCM (Greten, 2009).

One of the main orb involved in the mammary gland function is the stomach orb. As this gland is responsible to produce milk from *Xue* (“blood”), as this is a metabolic process, the phase Earth is involved. On the other hand, as it is located in the exterior part of the body, the extimal orb of the Earth phase dominates - the Stomach orb. This orb

produces fluids and reduces swellings so, when this function is affected, the breast dries up and cysts may develop.

Another important orb involved in the genesis of tumours is the Felleal orb (Gall bladder). In breast area, the conduit of Felleal orb runs parallel to the stomach conduit. The Felleal orb is the representation of the phase wood in the exterior, and is responsible for the smooth flow of *qi* and *xue*.

Feelings of helplessness, anger, frustrations, lack of emotional attention, conflicts may result in stagnations of *qi* and *xue*.

Greten (2009) also refers that *qi* and *xue* stasis and *ying* aberrations (genetic mutations) are some of the main causes for development of cancer. Accordingly to the same author, Felleal disorders frequently are accompanied with Pulmonary symptoms in particular when feelings of helplessness are present, leading to Wood-Metal imbalance.

Indeed, the Pulmonary orb is responsible for the defensive *qi*, moving the *qi* on the surface. As referred before the defensive *qi* moves and disperse the constructive *qi*, when this not occurs adequately it may appear signs of stagnation and accumulations.

Further influences came from the tenuiintestinal orb, the extimal representation of the phase fire. In this case we have a depletive cardiac orb and a relatively repletive tenuiintestinal orb. This can occur for example in cases of emotional over challenge, overwork and exhaustion. Accordingly to Greten (2009), this situation can develop a congestion in the mammary gland.

Also the renal orb is involved as the state of yin deficiency cause instable regulation overall, known as a risk factor of breast cancer (Greten, 2009). Accordingly to Porkert, the renal orb “represents the totality of physical, i.e. somatic, bodily substratum; it is the resource potential of all vital manifestations” (2001, p.124). The same author refers that, dysfunctions of the renal orb essentially arise when its storage capacities of energies received at birth is affected. Effectively, yin corresponds to structive, material, somatic aspects, that when is affected destroy the orthopatic structure of bodily substratum, a so called “depletion of yin” (Porkert, 1995).

3 – QIGONG

3.1. - Overview

Qigong is one of therapy of TCM; the Word is composed of two Chinese characters, *Qi* and *Gong*. *Qi* is often translated as energy and *Gong* as work, so to describe that it means the work on energy.

It is an ancient Chinese art and science working true posture, movement, breathing and meditation. As a biofeedback therapy, qigong activate psycho physiological self-regulation to restore or maintain a healthy balance overall (Greten, 2009). Those exercises can be done sitting, standing, moving or lying down.

Qigong is a set of internal exercises to cultivate the Three Treasures, which are the hallmarks of mental and physical health of human beings. In China, health and longevity are determined by the strength, balance and cultivation of those three treasures called: *Jing*, *Qi* and *Shen*, representing the human being holistically (Pedreros, 1992).

According to the same author, regular practice of qigong activates the internal *Qi* flow along the conduits, strengthens internal organs, maintains the vigour of body and mind, exercises the joints, muscles and tendons, prevent diseases caused by physical stress and promotes postural awareness.

MacRitche (1994) defends that, the practice of qigong promotes positive feelings, a sense of clarity and relaxation.

Qigong is considered a method of self practice or process by which one cultivates the *Qi* and *Yi* (consciousness or intention) with the aim of achieving an optimal state of health of body and mind (Chen, 2002).

There are historical references of qigong practice since ancient times, being that, according to Barroso (2006), one of the earliest references is made by a tribe called Tao Tang. Accordingly to the same author, in a citation of the work *Annals of Spring and Autumn* of Master Lu, a classic written around the year 230 BC, it is stated that “a long time in Chinese antiquity, people used a dance to strengthen the body, regular breathing, activate blood circulation and sometimes treat certain diseases”(Barroso, 2006, p.14).

Qigong is often translated as a set of breathing exercises, and in the field of Chinese Medicine refers to a term that nourishes and sustains the *Qi*.

From a TCM point of view, qigong has the functions of activating the body’s vital force (*qi*), strengthening the blood’s circulation, balancing yin and yang, stimulating the

conduits and improvement psychological state (Tsang, 2003). Effectively, associations and thoughts are necessary but have to be limited, otherwise people become less focused on their objectives and work, may have concentration problems, over-intensive dreams, among others (Posadzki, 2010). In TCM this capacity is a function of *Shen*. *Shen* is a special kind of capacity, originated by the cardiac orb that stands for the ability to limit and control emotions and associations in order to create a mental and emotional state of presence (Greten, 2009). According to the same author, qigong is one method of exercise to overcome this mental-emotion state.

These skills are acquired through regular practice of long term specific exercises. There are hundreds of different forms of qigong in China and, most of them are not intended to treat any specific disease but are used almost as prophylactic meditative exercises. Although the majority of styles of qigong promotes and benefits the health of a person, therapeutic qigong is a smaller specialize area specifically developed for treatment of diseases. The therapeutic qigong refers to the forms used by qigong practitioners who emphasize the health promotion and disease prevention. Qigong exercises should be based on three main aspects, harmonize breathing, body and mind (Dorcas, 2003). In fact, all qigong exercises are, in one form or another, closely related to the movement of breathing. In TCM is believed that by breathing we let the qi of conduits flow, and consequently protect the body from external agents. This function of clearing belongs to the pulmonary orb. So breathing can be considered a pacemaker of vegetative functions. On the other hand, if this function is insufficient, relieving does not take place and according to Greten (2009, p.36) “a relative accumulation of unrelieving, of maeror will remain within the psyche”.

The postures and body movement promote a state of relaxation, reducing muscle tension, gradually increasing the flexibility. Regarding the third aspect of harmonization of mind, Posadzki (2010), in a qualitative study entitled “The sociology of Qigong”, says that the regular practice of qigong promotes self discovery and increases well-being, although their practitioners develop more flexibility and adaptability in their thoughts, emotions and behaviours. It also says it strengthens the mental processes preventing diseases of that kind, relieves stress, anxiety and depression.

It works as a system of biofeedback, proprioception of vegetative system that allows a deep and higher consciousness and sensibility of the body, promoting a conducted focus. In the early 1950s scientists in China began investigating the many medical benefits claimed for qigong. Clinical and experimental evidence shows that qigong exercise can affect various functions and organs of the body.

Some of the functions and organs affected by qigong, and the measurements techniques employed, include electroencephalogram, termography, blood pressure,

electrocardiogram, ultrasonic cardiogram, enzyme activity, immune function, sex hormone levels, among others. Then, some of clinical and experimental researches studies will be describe to illustrate the scope of research on medical applications of qigong:

***Therapeutic balancing of conduits and functions of body**

It is known that the electrical conductance of the skin above individual acupuncture points is measured using low voltage and low current – electro acupuncture according to Voll (EAV).

So by this, when it exists a degeneration of an organ an “indicator drop” may occur consisting of an important diagnostic criteria. According to Sancier (1994), measurements were made by EAV in acupuncture points in individuals before and after practiced qigong, and those preliminary results show that qigong can decrease the average of the EAV measured values, decreasing “indicator drops”.

***Hypertension**

Wang et al (1993), reported a 30 year follow up study on 242 hypertensive patients who were divided randomly into a qigong group and a control group. They verify that blood pressure of the qigong group stabilized, whereas that of the control group increased and even relatively to drug dosage, the qigong group decreased or eliminated while in control group had to be increased.

***Sex Hormone levels**

One consequence of aging is that levels of sex hormones change in unfavorable directions.

Studies indicate that this trend can be reversed by qigong exercise as illustrated by Kuang (1991) in their study “Research on the antiaging effect of qigong”.

***Bone density**

Aging may result in a decrease in bone density, especially in women, as a consequence, bones become more brittle and subject to fracture.

Xu (1994), in a study to verify the changes in bone density in male subjects who practiced qigong for 1 year compared with healthy male subjects of the same age, found that bone density increase in male who practiced qigong for 1 year.

This traditional way of work with the vegetative system of biofeedback allows the optimization of the individual concepts of health.

3.2. - Qigong versus cancer

As previously mentioned, the regular practice of qigong is beneficial to health and helps prevent disease, but even in China, is less known its effects has an adjuvant in treating various diseases, e.g. cancer.

Most cancer treatments are effective in controlling symptoms or prolong life expectancy but bring negative consequences, as stated before, thus, the emergence of an effective non pharmacological therapy without side effects may have a major impact on cancer treatment.

Effectively, in the last years, in the field of modern medicine, comes an approach for treatment of cancer under the model of psychoneuroimmunology, that considerer the condition of whole person as the environment for the cancer and to strengthen the body`s resistance to cancer. Relies on many factors such as, exercise, diet and meditative states. qigong is part of this approach.

As the term psychoneuroimmunology indicates, implies the psychological and physiological mechanisms, as they operate in an interdependent way.

Qigong as a therapy within the TCM looks promising in the treatment of cancer and several studies conducted to date, have reported improvements with no side effects in patients who regularly practice qigong. Accordingly to Sancier (1999), a review of clinical studies on the therapeutic role of qigong exercises done in conjunction with drug treatment in cancer patients showed that even during chemotherapy, those who practiced qigong had fewer chemotherapy side effects than the group who only took their medication.

There are numerous mechanisms described by which the exercise in general improves the physiology of the human being, for example reducing the amount of fat, considered one of the main storage sites for toxins, thus, any type of activity and movement is itself, seems to be a great way to “detoxify” the body (Barnard, 2006).

Referring to hormone levels in the body, the practice of physical activity, reduces excess of estrogen and testosterone hormones sometimes involved in neoplastic processes, such as breast, prostate, ovary cancer, among others (Friedenreich, 2002).

According to the same author, the association and the scientific evidence between physical activity and cancer is categorized by the World Cancer Research Foundation and American Institute for Cancer Research as, “convincing”, “likely”, “possible” and “insufficient”, respecting to breast cancer is classified as “convincing”. Indeed, over 20 studies in this area demonstrated that association; of 44 studies conducted, it was observed in 32 to reduce the risk of breast cancer in women more physically active in likely 30-40% of the risk (Friedenreich, 2002).

Exercise/movement also reduces the level of blood sugar and consequently insulin secretion that contributes for inflammation of tissues and development and dissemination of tumors; acts directly in citoquines responsible for the state of inflammation, lowering its levels in the blood (Barnard, 2006).

The same author claims that, in an editorial of *Oncology, The Journal of Clinical Oncology*, regular practice of exercise significantly reduces the risk of recurrence around 50-60%.

Exercises such as qigong, tai chi or yoga that gently stimulates the body, can be practiced by almost all patients with cancer. They are actually an essential aid in the development and harmonization of breathing and mood.

According to Chen (2002), from a review carried out on qigong therapy for cancer treatment, it was determined some of the mechanisms involved in this process. So it seems that through qigong therapy immune function is improved, as also is improved the microcirculation, particularly referring to blood viscosity, elasticity of blood vessels and concentration of platelets. In the same study, it is stated that through qigong therapy it can be adjust the microcirculation to a state considered optimal increasing the effectiveness of certain treatments, such as chemotherapy.

Accordingly to Dong's (1990), from a physiological point of view, qigong can strengthening and stabilize the endocrine system, therefore having a regulating effect on the whole body's metabolism. A study conducted by the Shanghai Institute of Medical Sciences, for the combined use of Chinese and Western Medicine, and the effects of qigong and tai chi chuan on elderly people's endocrine systems, revealed an increased capability of their pituitary, thyroid and sex gland (Dong's, 1990).

Another crucial explanation pointed by the author above mentioned, is that one of the important factors in cancer growth or not is the body's content of oxygen. So if we have sufficient amount of oxygen cancer cells may die, and otherwise when the body is deficient in oxygen, cancer cells grow. Gigong can produce an increase in the absorption of oxygen true the postures, movements and breathing.

It is also described that, this therapy increases the pain threshold in patients. Pain is one of the most frequent symptoms and, one of the major reasons why patients seek the so called complementary medicines (Lee, 2009).

In turn, Butow (2009) states that, and making a parallel with conventional medicine, the effectiveness therapy true qigong in cancer treatment has its origin in an integrated hypothalamic response, resulting in the homeostasis of the sympathetic and parasympathetic nervous system. This, in turn, causes a reduction in physical and emotional tension and enhances the immune system.

Chen et al (2002) did a literature review of more than 50 studies of qigong therapy in cancer treatment in China by dividing them into three categories: clinical studies with cancer patients, in vitro studies with cancer cells and further studies in live animals affected with cancer. Clinical studies involving observation of cancer patients who practiced qigong. From the review, they found that there is a consistent trend for the groups who practiced qigong in combination with conventional treatments had significant improvements and increased average life expectancy compared to those groups treated only with conventional treatments.

Another important aspect of the success of the therapy by qigong in cancer patients, is explained by Dong`s (1990). Accordingly, it seems that qigong is especially effective when trained in groups. The author refers that, group practice is the best way to arouse interest that helps one concentrate on doing the qigong exercises, and the cheerfulness produces a beneficial effect on the organism. It is described that as soon as one or two patients had shown good results, the rest of patients would be encouraged to have greater confidence and so a positive attitude. Also, if people practice qigong exercises alone and fail to achieve results, are more likely to become discouraged.

Therapy through qigong can be a valuable and indispensable in the treatment of patients with cancer, complementing conventional treatments.

Interest in the area of physical activity and movement as a way to prevent cancer is increasing. Together with other measures such as diet, smoking, practice of an activity/exercise may be a risk factor for development of a cancer that can be changed through a change in habits and lifestyle.

This is precisely what the resounding report from World Cancer Research Foundation emphasizes by stating at one point that “on principle the majority of cancers are preventable” (2007, p.10).

Each step toward facilitating a better balance to a large extent the following steps.

PART II

METHODOLOGICAL FRAMEWORK

4 – METHODOLOGY

4.1. - Objectives of the study and research question

The theme for this work was chosen having in mind the fact that there's no similar study known in the referred community.

Recognizing technical and scientific advances at health's level in general and oncology in particular, health promotion and disease prevention assumed to be pillars in fighting against cancer, particularly through acquisition of healthy lifestyles. Indeed, women with breast cancer increasingly need a holistic way of care, characterized by a continuous care throughout the process and experience of the disease.

In this context emerges the importance of the integration of complementary medicines such as TCM, in the treatment of various diseases, e.g. cancer.

Thus, the present study aims to objective and subjective assess the qigong related effects in breast cancer patients, and also to contribute to the promotion of effective interventions in those patients, in a multidisciplinary and interdisciplinary perspective.

The research question is:

»» How can we objectively and subjectively assess the qigong related effects in breast cancer patients?

Defining the following objectives:

*Evaluate the influence of regular practice of qigong in quality of life of breast cancer patients;

*Evaluate the influence of regular practice of qigong when assessing shoulder's range of motion in the affected side;

*Evaluate the influence of regular practice of qigong in the salivary cortisol level.

The purpose of this study is to:

*Contribute to improvement of MTC care in breast cancer patients.

4.2. - Type of study

Such research focuses on unique and singular persons, with their own experiences wrapped in a very specific context. Bearing in mind the characteristics and specificities of this study, we chose a quantitative approach.

According to Ribeiro (2008, p.79), "quantitative research is characterized by expressing itself through numbers or abstract entities", referring to variables meaningful to the conducted research. Given these principles, quantitative methodology seeks a particular understanding of the studied reality, being this the main concern of this study.

In this work we intend to study and deepen knowledge on the topic selected and understand the phenomena. We're not trying to give explanation or even make any kind of generalization, but explore the topic in question and, specially, trying to create new avenues for understanding the phenomena. Finally, to improve the care practice in TCM, specifically regarding the practice of qigong.

According to Fortin (1996, p.193), the type of study "describes the structure used according to the research question, aims to describe variables or groups of subjects, explore or examine relationships between variables or to test hypotheses of causality." It is an exploratory, descriptive and transversal study, describing experiences and which aims "to describe a population or envision a situation" (Fortin, 1996, p.138).

Having an exploratory nature and given the scarcity of studies conducted on this subject, the study aims to provide greater familiarity with the problem in order to make it more explicit (Gil, 1994). It represents a study case that can be defined as an in-depth study of a single case or few cases (Barden & Abbot, 2002).

The study case does not allow a generalization of findings to the population, neither determine the cause of behaviour, they're merely descriptive and useful to illustrate and support a theory. You could say that a study case should be considered as a unique sample of cases important to illustrate theories, or to describe conditions that fall outside of the theories and which may support the new theories.

4.3. - Study variables

The variables selected in the present work were:

*Main variables:

- Quality of life of breast cancer patients
- Mobility of the affected breast side shoulder
- Cortisol level in saliva

*Socio-demographic variables:

- Age
- Marital status
- Household
- Education
- Current situation of employment
- Place of residence
- District of usual residence

*Clinical variables

- Date of diagnosis
- Purpose of chemotherapy treatment
- Number of cycles of chemotherapy performed
- Type of surgery
- Time elapsed since surgery
- Other treatments (radiotherapy, hormone therapy)
- Associated illness diagnosed
- Current metastatic disease
- Sites of metastasis

*Secondary variables

- Physical exercise

4.4. - Population and sample

The obtainment of a sample was possible through a set of actions, from the definition of target population until the establishment of individual and institutional contacts.

The present study examined a sample of women with breast cancer, patients in the breast clinic of the Portuguese Institute of Oncology in Porto. Nowadays, the referred institute treats about 4500 cancer patients per year and about 1000 of them are patients with breast cancer. Is the only unit that handles the largest number of patients with breast cancer in Portugal and one of the largest in Europe (www.ipoport.pt). The breast clinic is a multidisciplinary unit specialized in providing high quality health care, embodying adequate human and technical resources necessary to an integral approach of patients with breast cancer, from the early diagnosis until the treatment in advanced stage of disease.

According to Fortin (1996), population is a set of elements or individuals that share common features, defined by a set of criteria; hence, it is an intentional sample, also called a convenience sample. In this kind of sample, the relative probability of any element be included in the sample is unknown. The main problem is that there's no record of how much it is representative of a population or universe (Smith, 1975).

The sample consisted in 11 elements in the qigong group and 5 elements in the control group, who went to an appointment at the breast clinic during the period of data collection.

The criteria used to select the sample were:

- *Age > 18 years
- *Physically fit for exercises
- *written consent
- *Chemotherapy planned
- *Surgery at least 3 months

Would be excluded of the research who had at least one of the following criteria:

- *Suffer from psychiatric significant disease
- * Have medical contraindication

The control sample was fulfilled with elements that meet the criteria of inclusion but did not demonstrate the desire/willingness to carry out the intervention with qigong.

4.5. - Strategy for collecting data

Data from a study are "information elements obtained during the investigation" consisting in concepts or variables (Polit and Hungler, 1995, p.25).

In this work, and given the issue related to it, the basis of data collection was introducing a self-administered questionnaire by the patient. But other media have been driven, in particular the consultation of the clinical process to obtain the most reliable data possible. When applying the questionnaires to studied individuals, was attended the general principles contained in any research and referenced by Bogdan and Biklen (1994, p.77). "... the individuals identity should be protected ..." in order to keep confidentiality of information, to assure patient's confidentiality and respect for privacy. Patients complete a questionnaire and shoulder range of motion is measured. A sample of saliva is collected.

After the presentation of the investigator, were explained the study objectives, emphasized the confidentiality of data and the free participation in the study, assuring anonymity on the use of data.

To "negotiate an authorization to conduct a trial and regarding the termination of the agreement, the investigator must be clear and specific with all stakeholders, and must respect it until the conclusion of the study" (Bogdan & Biklen, 1994, p.77). Respecting the individuals' decision to participate or not in the study, they're informed of the opportunity to leave the study at any time during the process, and also that all information obtained would only be used for the purpose it was intended.

To collect data and realize the intervention, it was requested for permission to carry them out at the Portuguese Institute of Oncology in Porto (Annex I).

After the formal request, that justified its importance and objectives and requested permission for the need for consultation of medical records, is obtained approval for its implementation (Annex II).

The period to obtain this data was from 21 February 2011 to 11 March 2011.

4.6. Collect data instruments

Assessing quality of life in experiences of cancer is not an easy task, even if the time of survival in oncology is usually the most used indicator to assess the effectiveness of interventions. With the approval of quality of life questionnaires, there is the opportunity to assess the influence and effectiveness of cancer treatments in other ways.

To select the instruments, it was considered their suitability in assessing the variables, their structure and their national and international use. The instruments validity and other metrics characteristics must always be measured in the culture where it will be applied.

The instruments used in the present investigation were the following:

- * Socio-demographic and clinical questionnaire, created for the purpose of the study (Annex III and IV);
- * Quality of Life QLQ-C30 and QLQ-Br23 questionnaires, created by the Cancer Study Group on Quality of Life of European Organization for Research and Treatment of Cancer (EORTC) (Annex V)
- *Evaluation of joint range of motion of the breast affected side – goniometry
- *Laboratorial tests of measurement of salivary level of cortisol

Were directly requested to the EORTC the scales used which were provided and authorized to carry out in this work.

The questionnaire is a form of data collection that consists of gathering information, translating the objectives of a study with measurable variables. Helps to organize and control data, so that the information sought can be collected in a rigorous manner (Fortin, 1999).

Was requested the collaboration of the chemistry laboratory of the Hospital of Santo Antonio do Porto to determine the levels of salivary cortisol.

4.6.1 - Psychometric characteristics of the instruments

Here are described the characteristics of the instruments used in the present study.

Socio-demographic and clinical questionnaire

The socio-demographic and clinical questionnaire was built for this investigation to access the socio-demographic and clinical variables of the patients; these last inherent to breast cancer pathology.

The socio demographic variables assessed were age, marital status, household educational level, employment status, place and district of residence and practice of physical exercise. Each one of those variables was categorized according to different dimensions. Firstly, the variable age was divided into four classes: "18-38", "39-59", "60-80", ">80", defining the variable age group. For marital status were considered the following classes: "single", "married", "fact union", "divorced" and "widower". For household was considered the following categories: "Husband and children", "husband", "lives alone" and "others". For educational level it was adopted the following: "cannot read or write", "can read and/or write", "1st -4th year", "5th-6th year", "7th-9th year", "10th-12th year", "university" and "postgraduate training". For the employment status it was considered the dimensions: "active", "active/sick leave", "unemployed", "pensioner" or "other situation". The place of residence was distinguished between urban and rural areas, while the district of residence was placed as an open question. The last one, for practicing of physical exercise was considered the categories: "never", "once a week", "2 times a week" or "more than 2 times a week". And the modality of exercise was an open question.

Simultaneous to this questionnaire, was used a record sheet of some clinical data that were considered relevant to this research work, such as date of diagnosis, purpose of chemotherapy, number of chemotherapy cycles carried out, diagnosed diseases, breast surgery, type and date, other treatments (radiotherapy and hormone therapy) and presence or absence of metastasis. To do so, it was consulted the clinical process of the patient.

Questionnaire - QLQ-C30

As cancer becomes a chronic disease and more people diagnosed with cancer survive each year, the evaluation of quality of life becomes an important end point. Quality of Life was measured using instruments developed by the Cancer Study Group on Quality of Life of European Organization for Research and Treatment of Cancer (EORTC, 2001). The EORTC is an international non-profit organization aiming to conduct, develop, coordinate and stimulate cancer research carried out in Europe.

The QLQ – C30 is considered a questionnaire for assessing QoL in patients with cancer, consisting of 30 items, divided by a global scale, five functional scales (physical, role, emotional, cognitive and social functioning), and sub-scales of symptoms associated with cancer and treatment (Table 3).

Item/subscales	Items	Total items
Item/Functional subscales		
Physical functioning	1, 2, 3, 4, 5	5
Occupational functioning	6, 7	2
Emotional functioning	21, 22, 23, 24	4
Cognitive functioning	20, 25	2
Social functioning	26, 27	2
Items/Symptoms Subscales		
Fatigue	10, 12, 18	3
Nausea and vomiting	14, 15	2
Pain	9, 19	2
Dyspnoea	8	1
Insomnia	11	1
Loss of appetite	13	1
Constipation	16	1
Diarrhoea	17	1
Financial difficulties	28	1
Overall state of health	29, 30	2

Table 3- Items/Subscales of QLQ-C30 questionnaire

The answer format is a 4-point likert type (from “not at all” to “very much”) for the functional and symptoms scales, and 7 point linear analogue scale (from “bad” to “optimum”) to global health. It is a questionnaire considered appropriate for use with cancer patients from the moment of diagnosis to long survivorship. The structure of the questionnaire was used in an international study of 305 cancer patients, with the exception of the sub-scale of paper function, for low internal consistency (Aaronson et al, 1993). According to the author, the reliability and validity of the questionnaire were highly consistent across the three language-cultural groups studied.

Another study from Pais Ribeiro (2007) with 933 cancer patients have also maintained the structure of the questionnaire revealing good levels of internal consistency as shown in the table below (Table 4):

Scale	Description	Intern consistency (Study 1)	Intern consistency (Study 2)
Global Health scale 2 items: 29, 30	Evaluate the global health state	0.86	0.88
Physical 5 items: 1,2,3,4,5	Evaluates the physical level	0.68	0.74
Role 2 items: 6, 7	Accesses the level of functioning in roles played in profession and leisure	0.54	0.85
Emotional 4 items:21, 22, 23, 24	Evaluates the emotional level	0.73	0.87
Cognitive 2 items: 20, 25	Evaluates the cognitive performance	0.56	0.57
Social 2 items: 26, 27	Evaluates the social performance	0.68	0.78

Table 4 - Description of global and functional scales of the QLQ-C30 and values of internal consistency Study 1: Aaronson, N. et al., 1993 (n=305); Study 2: Pais-Ribeiro, Pinto & Santos, 2007 (n=933)

According to Pais-Ribeiro (2007), their studies suggest that the questionnaire for the assessment of health reported quality of life QLQ-C30 is an appropriate instrument to measure QoL of Portuguese cancer patients; behaves the same way in very different cultures and languages; is sensitive to different cancer sites and is not sensitive to stages of survivorship.

Considering the module QLQ-Br23, more specifically the quality of life of patients with breast cancer, it was found that, similar to what happens with the QLQ-C30, also has 23 items divided into two major groups of subscales (Table 5). The answer to each of these items is also given through a likert scale with four alternatives in which the extremes are “not at all” and “very much”.

Item/subscales	Items	Total items
Item/Functional Subscales		
Body image	39, 40, 41, 42	4
Sexual functioning	44, 45	2
Sexual enjoyment	46	1
Future prospects	43	1
Items/Symptoms Subscales		
Effects of systemic therapy	31, 32, 33, 34, 36, 37, 38	7
Breast symptoms	50, 51, 52, 53	4
Arm symptoms	47, 48, 49	3
Hair loss	35	1

Table 5 - Items/Subscales of QLQ-Br23 Questionnaire

The analysis of the results of these rating scales provided by the EORTC, was conducted according to their own statements (EORTC Scoring Manual, 2001). It was made the application of two mathematical formulas for determining the scores of several items and several subscales of response.

Thus, in relation to functional subscales it was applied the following formula: $(1 - (\text{rawscore} - 1) / \text{range}) * 100$; At the same time, relatively to the subscales of symptoms, was applied the following formula: $((\text{rawscore} - 1) / \text{range}) * 100$. In these two formulas, the “raw score” is the arithmetic average of various items that compose each of the various subscales, while the “range” is the difference between the maximum possible value and the minimum value possible for each of the items. By applying these mathematical formulas, we obtain scores that were calculated using a computer program. That scores range is between 0 and 100, as indicated in the manual for quotation (EORTC, 2001).

In both questionnaires, a high score for the functional subscales and global health state means that there is a good performance by the individual for this subscale. A high score for the subscales of symptoms means that this particular symptom interferes with the very life of the individual or because is often present or has a great intensity.

Assessment of shoulder range of motion – goniometry

As mentioned along the theoretical framework, the decreased range of motion in the shoulder joint ipsilateral to surgery is one of the most common complications in patients with breast cancer, thus pointing to the great need of assessment, guidance and execution of specific movements / exercises.

The functional examination performed in the present investigation includes the evaluation of range of shoulder movement using a goniometer. Goniometer is a word derived from the junction of *Gonio* which means angle and *metria* which means measure, i.e., goniometry allows us to quantify / measure the different articular angles, decide the specific intervention, the most adequate and also document the efficacy of the treatment. The instrument used to perform this measurement is a goniometer. It consists of two arms and an axle; one of the arms follows the movement and the other remains still; the axle rests on the joint to assess. According to Marques (1977), it has the advantage of being an instrument with no high cost, easy to handle and the swift action to perform. From the goniometric specific tests is possible to obtain a framework of restrictions and recording the limitations.

The purpose is to evaluate the homolateral shoulder surgery and compared before and after the intervention with qigong.

The variables addressed in this study were: degrees of shoulder joint mobility of the affected side, range of motion of active flexion and abduction movement before and after intervention with qigong. Participants were subjected to those tests to assess the degree of mobility through goniometry.

In the flexion of shoulder, the movement occurs in the glenohumeral joint in the sagittal plane, accompanied by movements in the sternoclavicular, acromioclavicular and scapulothoracic joints. The joint amplitude goes from 0 to 180 degrees.

In the abduction of shoulder, the movement occurs in the frontal plane. The abduction of the glenohumeral articulation is accompanied by clavicular elevation followed by lateral rotation of the humerus. The range of motion varies from 0 to 180 degrees.

The normal range changes according to factors such as the age of the patient. Then, there is a table about the effects of age on the amplitude of shoulder movement according to 3 studies, in the flexion and abduction movement.

Movement	BOONE						WALKER ET AL		DOWNEY ET AL	
	20-29 years old (N=19)		30-39 years old (N=18)		40-54 years old (N=19)		60-85 years old (N=30)		61-93 years old (N=106)	
	Media	Standard deviation	Media	Standard deviation						
Flexion	164.5	5.9	165.4	3.8	165.1	5.2	160.0	11.0	165.0	10.7
Abduction	182.6	9.8	182.8	7.7	182.6	9.8	155.0	22.0	157.9	17.4

Table 6 - Influence of age on the movement of shoulder: average values in degrees from young to old from 20 to 93 years old (Norkin, 1997)

The average values of the table show a trend of older ages (60 years and older) that present smaller values of movement. On the other hand, concerning to the dates of standard deviation, it is shown that those in older groups are much larger than those in younger age.

Measurement of salivary cortisol level

Cortisol is the primary glucocorticoid hormone produced by the adrenal cortex, is secreted by the fasciculate area of the adrenal cortex.

Over the last decade the use of salivary cortisol as a biomarker for the study of stress and related diseases has become increasingly common. Salivary hormone measurement is convenient and non-invasive, and it makes possible studies that would be difficult with others methods.

Some of the main functions of cortisol are:

*Proper glucose metabolism

- *Regulation of blood pressure
- *Insulin release for blood sugar maintenance
- *Immune function
- *Inflammatory response

(Nieman, 2010)

Salivary cortisol concentrations vary during the day. Normally, is present in the body at higher levels in the morning (about 5,6 ng/ml – 15,4 nmol/L), and lowest at night (about 1 ng/ml – 2,8 nmol/L) (Nieman,2010). Although stress isn't the only reason for what cortisol is secreted, it has been termed "the stress hormone" because it's also secreted in higher levels during the body's response to stress, and it's responsible for several stress changes in the body. Acute physical or psychological stress activates the hypothalamic-pituitary-adrenal axis, resulting in increased plasma ACTH and cortisol concentrations. (Southwick, 1998)

That is the reason why cortisol levels are sometimes measured to determine how much stress a person experienced. Unrelenting stress can cause increased cortisol levels. Although knowing that the activation of the cortisol as a response to stress is protective in a short period of time, extreme or chronic activation can have negative consequences in long-term period (Soutwick, 1998). According to the same author, small increases of cortisol have some positives effects:

- √ Quick burst of energy for survival reasons;
- √ Heightened memory functions
- √ A burst of increased immunity
- √ Lower sensitivity to pain
- √ Helps to maintain homeostasis in the body

While cortisol is an important and helpful part of the body's response to stress, it's important that the body's relaxation response should be activated, so the body's functions can return to normal following a stressful event. In our current high-stress culture, the body's stress response is activated so often that the body doesn't have the chance to return to normal level, resulting in a state of chronic stress (Southwick, 1998).

Higher and more prolonged levels of cortisol in circulation, like those associated with chronic stress, have been shown to have negative effects such as:

- × Impaired cognitive performance
- × Suppressed thyroid function
- × Blood sugar imbalances
- × Decreased bone density
- × Decrease in muscle tissues

*Higher blood pressure

*Lower immunity and inflammatory responses in the body, slowed wound healing

*Increased abdominal fat

(Soutwich,1998).

In fact, serum free cortisol diffuses freely into saliva. Therefore, measurements of salivary cortisol more accurately reflect serum free cortisol concentrations than do measurements of serum total cortisol. An important advantage of salivary dosage is that cortisol in saliva is 100% free and biologically active (King1, 2000). According to the same author, stress causes a reduction in salivary flow, which can change the concentrations of some substances found in the saliva. However, the flow of saliva has no effect on salivary cortisol levels, because the small size and high lipid solubility of molecules present in cortisol facilitate diffusion through cell membranes to the secretory saliva. To keep cortisol levels healthy and under control, the body's relaxation response must be activated after the stress response occurs. This can be achieved learning to relax the body with various stress management techniques and making lifestyle changes (King, 2000).

Saliva samples are obtained by simple procedures, non-invasive and can be performed by untrained persons, besides the fact that salivary cortisol samples are stable at room temperature for one week and can be transported to the laboratory by mail or carrier (King, 2000).

4.7. – Intervention

Patients assigned to the intervention group received usual medical care and were invited to attend one group of therapy by qigong, held in the hospital where they were treated.

The qigong program runs for 5 weeks with 2 sessions per week of 45 minutes. The qigong intervention program is a modified traditional qigong program developed specifically target the needs of cancer; each session consist of several exercises selected for the case, that can be found in *"Handbook of functional therapeutic Qigong I – Exercises according to diagnosis* from Greten (2009).

Participants assigned to the control group receive usual care and complete all outcome measures at the same time frame as the intervention group. Usual care comprises appropriate medical intervention without the offer of additional qigong program. Participants in the control group continued with their usual daily tasks.

4.8. - Ethical Implications

When people are involved in a study, there are certain rights that the researcher has to meet and respect. Fortin (1996, p.128) considers that "the rights of the person who should be absolutely protected in research protocols involving human individuals, are the rights to self-determination, privacy, anonymity and confidentiality, protection against discomfort and injury as well as the right to a fair and equitable treatment. "

Ethical rigors of confidentiality and anonymity of the participants were followed in the present study, thus, all the names of actors were replaced by letters and numbers. Intervention begins after proper authorization from the hospital administration; then, the work objectives and data collection method are explained, asking for their participation and consent (Annex VI).

5 – RESULTS AND ANALYSIS

The data presented are organized to respond to the research question that guided the study. The presentation of results begins with a general characterization of the sample concerning to the socio-demographic and clinical variables. It follows the presentation of results itself.

5.1. – Socio-demographic characterization

It appears, then, in a descriptive way the socio-demographic sample variables (Table 7). Regarding the age criteria, different groups were defined. In both groups (qigong and control), the dominant age group was between “39-59” years old, which corresponds to 72,7% and 80% in qigong and control group, respectively. Regarding marital status, in both groups, the largest percentage are married, 54,4% in qigong and 80% in control group, living the majority with husband and children, 54,5% in qigong and 60% in control group. On education, in the qigong group, the dominant group is “7th - 9th” grades (27,3%) and “9th -12th” grades (27,3%), and 18,2% with academic degree. In control group, the majority (40%) has between “1st - 4th” grade, and none have academic degree. So, for this work, in qigong group, were shown that most users are retired (54,5%), while in control group, only 20% are in that condition, being that 40% are unemployed and another 40% are still active. This may explain, mostly, the lack of availability of the users belonging to the control group to join a group of qigong. Regarding the residence place, it seems that most of qigong group elements live in urban areas (90,9%), whereas in control group, dominates the rural areas of residence (60%). With regard to physical exercise, the majority never perform any kind of physical activity, meaning 45,5% in qigong group and 60% in control group.

Socio-demographic characteristics		Qigong group (n=11)		Control group (n=5)	
		Frequency	%	Frequency	%
Age group	18-38	1	9,1	-	-
	39-59	8	72,7	4	80,0
	60-80	2	18,2	1	20,0
Marital status	Married	6	54,5	4	80,0
	Divorced	5	45,5	1	20,0
Household	Lives alone	2	18,2	-	-
	Husband	-	-	1	20,0
	Husband and children	6	54,5	3	60,0
	Others	3	27,3	1	20,0
Education	1st-4th Grade	2	18,2	2	40,0
	5th-6th Grade	1	9,1	1	20,0
	7th-9th Grade	3	27,3	1	20,0
	10th-12th Grade	3	27,3	1	20,0
	Academic degree	2	18,2	-	-
Current employment status	Unemployed	1	9,1	2	40,0
	Active	4	36,4	2	40,0
	Retired	6	54,5	1	20,0
Place of residence	Urban area	10	90,9	2	40,0
	Rural area	1	9,1	3	60,0
Physical activity	Never	5	45,5	3	60,0
	1x week	4	36,4	-	-
	2x week	1	9,1	1	20,0
	>2x week	1	9,1	1	20,0

Table 7- Socio-demographic characteristics

5.2. - Clinical data characterization

The clinical data sheet addresses issues related to disease and treatments (Table 8).

Relatively to the time elapsed since diagnosis, in 54,5% of qigong sample, this was performed in a period of “1 to 5 years” and, in 36,4% were diagnosed less than one year, being that only in 9,1% of the cases the diagnostic was made over 5 years; on the other hand, in 80% of control group, the diagnosis was made less than 1 year and no one was made for more than five years. In qigong group, 90,9% of users do not have metastatic disease, in control group no one have.

Concerning the treatment characterization these patients have done or are doing, we can see some more specific aspects. The whole sample performed breast surgery for

at least 3 months, being that in qigong group, 72,7% performed breast conservative surgery and 27,3% radical surgery, while in the control group 60% performed radical surgery and 40% conservative breast surgery.

With regard to other kinds of treatments, all users have made chemotherapy treatments, and in the qigong group, 54,5% underwent radiotherapy and 45,5% hormonal therapy. In control group, 80% have not made radiotherapy or hormone therapy, which is justified by the latest time of diagnosis in this group. Note that all users have done more than one kind of treatment.

Concerning to chemotherapy protocol, it was found that in 90,9% of cases of qigong group is adjunct, being that in control group all of the users are, since the aim is the complete remission of the disease. On the other hand, in 9% of the total sample group of qigong, the treatment is considered the 2nd line, due to metastatic disease, such as palliative care.

In relation to the number of cycles of chemotherapy that the users of the qigong group made as early intervention, it was found that in 54,5% the users did six cycles and 45,5% only one cycle; in the control group, 80% had made only one cycle and only 20% performed three cycles of chemotherapy.

Regarding the existence of associated pathologies, it was found that there are no associated pathology in 36,4% and 20% of the cases of qigong and control group, respectively, and, in cases where there is the presence of associated pathology, most in the qigong group, is related to digestive disease (18,2%) or other types of cancer (18,2%), and in control group, 40% also associated to digestive diseases and 40% to osteoarticular pathology.

Clinical data		Qigong Group (n=11)		Control Group (n=5)	
		Frequency	%	Frequency	%
Time since diagnose	< 1 Year	4	36,4	4	80,0
	1 – 5 Years	6	54,5	1	20,0
	>5 Years	1	9,1	-	-
Metastatic disease	Yes	2	18,2	-	-
	No	9	81,8	5	100,0
Surgery	Conservative	8	72,7	2	40,0
	Radical	3	27,3	3	60,0
Chemotherapy purpose	Adjunct	9	81,8	5	100,0
	2 nd line/palliative	2	18,2	-	-
Number of Chemotherapy cycles *	6 (six)	5	54,5	-	-
	3 (three)	-	-	1	20,0
	1 (one)	6	45,5	4	80,0
Radiotherapy	Realize	6	54,5	1	20,0
	Not realize	5	45,5	4	80,0
Hormone therapy	Realize	5	45,5	1	20,0
	Not realize	6	54,5	4	80,0
Other associated pathology	Yes	7	63,6	1	20,0
	No	4	36,4	4	80,0

Table 8 - Clinical data characterization

*Before Qigong intervention

5.3. – Quality of Life characterization according to QLQ-C30 and QLQ-Br23

The analyses of the results of data collection provided by the EORTC were carried out accordingly with the instructions of the scoring manual, also provided by that organization.

Questionnaire results analysis allows to users quality of life characterization.

It was also made the variation coefficient (VC) calculation as a measure of accuracy. Indeed, variation coefficient is a dispersion measure used to estimate the accuracy of experiments and represents the standard deviation expressed as a mean percentage (Mohallem et al, 2008). According to the same author, it allows results comparison involving the same response variable, allowing to quantify the accuracy of the research, that under equal conditions, is more accurate or uniform as low is the variation coefficient.

According to this data classification, the variation coefficient is considered low when is less than 10%, average between 10 and 20%, high between 20 and 30% and very high if more than 30% (Gomes, 1990).

The table below presents the survey data before and after Qigong intervention referring to QLQ C-30 (Table 9).

	Before Qigong						After Qigong					
	G. Qigong			G. Control			G. Qigong			G. Control		
	Rs	Score %	VC %	Rs	Score %	VC%	Rs	Score %	VC %	Rs	Score %	VC %
Functional subscales												
Physical functioning	1,71	76,36	35,8	1,76	74,67	26,1	1,58	80,61	5	2,12	62,67	13,8
Occupational functioning (role-play)	2,18	60,61	53,3	1,80	73,33	11,1	2,05	65,15	15	2,20	60,00	2
Emotional functioning	2,27	57,58	21,65	1,85	71,67	37,65	2,05	65,15	3	2,55	48,33	4,25
Cognitive functioning	2,18	60,67	34,9	1,50	83,33	20,1	1,69	77,17	13	1,70	76,67	4
Social functioning	1,78	74,17	38,6	1,20	93,33	21,4	1,73	75,67	10	1,50	83,33	6
Symptoms subscales												
Fatigue	2,33	44,44	28,83	1,80	26,67	11,1	2,03	34,33	11,67	2,67	55,56	1
Nausea, vomiting	1,23	7,50	13,5	1,20	6,67	21,4	1,41	13,50	15	2,10	36,67	22
Pain	2,14	37,83	56,8	1,60	20,00	16,25	1,64	21,33	19,5	2,40	46,67	1
Dyspnoea	1,73	24,33	58,9	1,4	13,33	21,4	1,36	12	5	1,4	13,33	6
Insomnia	2,55	51,67	26,4	2,00	33,33	50	1,91	63,67	4	2,2	40	22
Loss of appetite	1,73	24,33	70,5	1,6	20	18,8	1,45	15	15	2,2	40	2
Constipation	1,64	21,33	40	1,6	20	50	1,27	9	4	1,6	20	40
Diarrhoea	1,27	9,0	17,1	1	0	0	1	0	0	1,2	6,67	3
Financial difficulties	2,27	42,33	36	2,2	40	31,8	2,27	42,33	8	2,6	53,33	3
Global health status												
General health	3,7	45	59,5	3,8	46,67	44,7	3,91	48,5	20	3	33,33	33
Overall quality of life	3,82	47	56,7	3,4	40	38,2	4,18	53	32	2,8	18	18

Table 9- Quality of life characterization according to QLQ-C30

In relation to functional subscales, it was found that, before the intervention, the best performance in qigong group was obtained in physical functioning with an average score of 76,36. The worst performance was observed in emotional functioning, with an

average score of 57,58. In the control group, is in social functioning that there is a high score of 93,33, with the worst performance also seen in emotional functioning with a score of 71,67.

With regard to evaluation after qigong intervention, in qigong group, the score has improved in all subscales being the improvement most evident in relation to cognitive and emotional functioning (Figure 4) with an average score of 77,17 and 65,15 respectively. It is also at the level of emotional functioning that lies a more homogeneous response with the lowest variation coefficient of 3%. In turn, in control group, there was a decrease in all scores, being that the most accentuated decline was seen in emotional functioning, with an average score of 48,33, it is also true homogeneity in the responses with a variation coefficient of 4.25%.

The data presented in the figure reflect the difference between the values obtained before and after the intervention with qigong, in both groups.

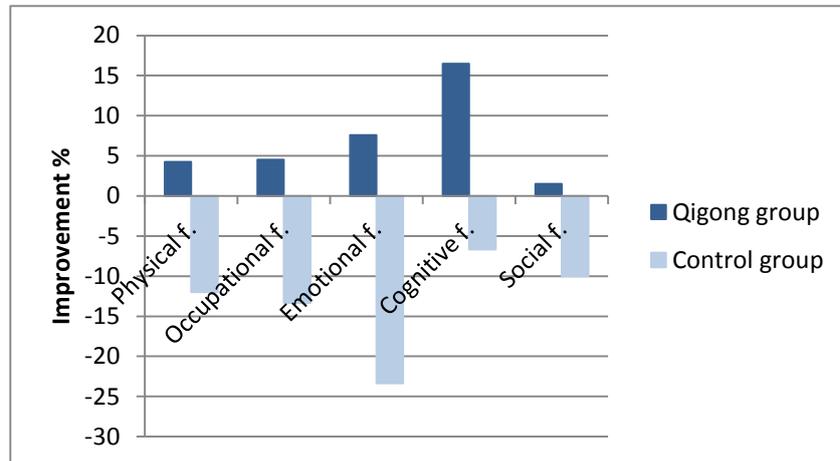


Figure 4 - Comparison of Qigong and Control groups in relation to functional scales of QLQ-C30

Regarding to symptoms items/subscales, it is shown that, before intervention, in both groups, insomnia and fatigue are the most frequent or more intense symptoms. After the intervention, in qigong group, insomnia was worse but fatigue was improved, whereas in control group, there was an aggravation of both symptoms. On the other hand, before the intervention, both groups show that nausea and vomiting and diarrhea were the less frequent or intense symptoms. After the intervention, in the second evaluation, it appears that in both groups, nausea and vomiting, significantly worsened, while diarrhea improved in qigong group (Figure 5).

Those results are consistent with the fact that the majority of users in this sample are starting chemotherapy treatments simultaneously with the qigong intervention beginning. Seeing how symptoms vary amongst individuals of the sample, we note that in qigong group, insomnia and constipation have the lowest variation coefficient ($VC=4$),

being that pain is the symptom with greater heterogeneity of responses ($VC=19,5$). In control group, fatigue and pain present lowest variation coefficient ($VC=1$) while constipation has a higher variation coefficient ($VC=40$).

In the chart below is also possible to observe the difference in values in the two assessments, in both groups.

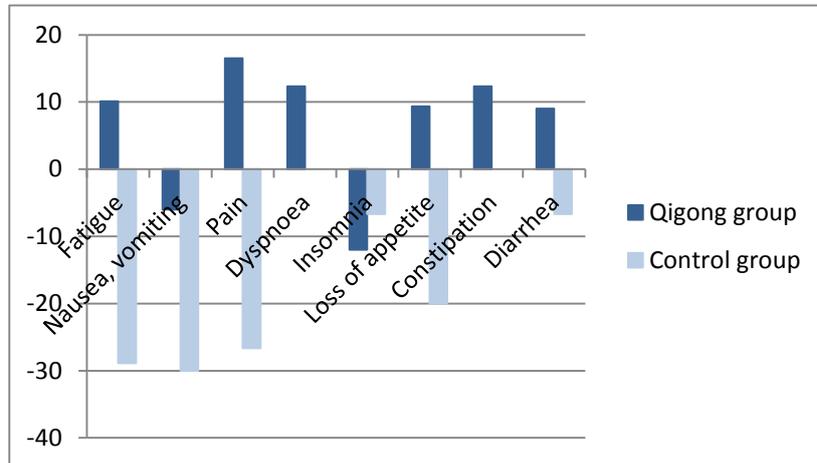


Figure 5 - Comparison of Qigong and Control groups in relation to symptoms subscales of QLQ C-30

With regard to assessing the overall state of health was found that, in qigong group improved, whereas in control group didn't happened the same. There was a worsening of health status in general and also the overall quality of life, as can be seen in the chart below (Figure 6):

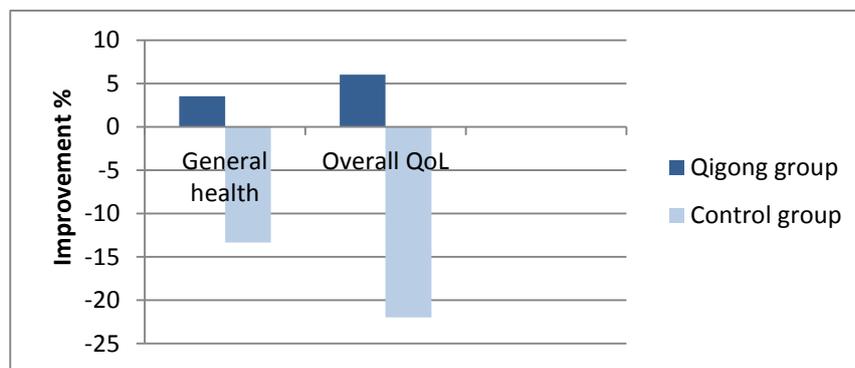


Figure 6 - Comparison of Qigong and Control groups in relation to Global health status

Through the application of QLQ-Br 23 questionnaire module, specifically related to quality of life of women with breast cancer, it was obtained the following expressed results (Table 10).

	Before Qigong						After Qigong					
	G. Qigong			G. Control			G. Qigong			G. Control		
	Rs	Score %	VC %	Rs	Score %	VC %	Rs	Score %	VC %	Rs	Score%	VC %
Functional subscales												
Body image	1,91	69,67	42,85	1,85	71,67	26,42	1,82	72,67	16,75	2,15	61,67	32,25
Sexual functioning	1,41	86	19,25	1,60	80	18,8	1,55	81,67	9,5	1,20	93,33	3
Sexual pleasure*	0,82	---	46,7	1	---	307,1	1	---	196	0,4	---	160
Future prospects	3,18	27	42,9	4	0	0	2,82	39,33	48	4	0	----
Symptoms subscales												
Eff. systemic therapy	1,71	23,79	34,93	1,37	12,38	35,37	1,57	19,03	28,57	1,86	28,57	3,43
Breast symptoms	1,66	21,97	38,1	1,75	25,00	57,13	1,18	6,06	2,5	1,75	25,00	20,75
Arm symptoms	1,82	27,27	20,47	2	33,33	13,9	1,61	20,20	3,33	2,13	37,78	8,33
Concern with hair loss*	0,55	---	22,2	0,8	---	0	1,09	3	109	3,2	73,33	1

Table 10 - Quality of life characterization according to QLQ-Br23

*Sexual pleasure, is not applicable if item 45 of questionnaire is "not at all"

**Concern with hair loss, is not applicable if item 34 of questionnaire is "not at all"

It was found that the best performance, before and after the intervention, was observed in sexual functioning, in both groups, and also the greater homogeneity of responses with a variation coefficient of less than 10 (VC=3). On the other extreme, the worst performance is observed at the level of future prospects in both groups and in the two moments of the intervention, before and after, although, as you can see from the chart below, the group of Qigong has improved perception of future life (Figure 7). The greater diversity of responses, considering the values of coefficient of variation, was at level of sexual pleasure.

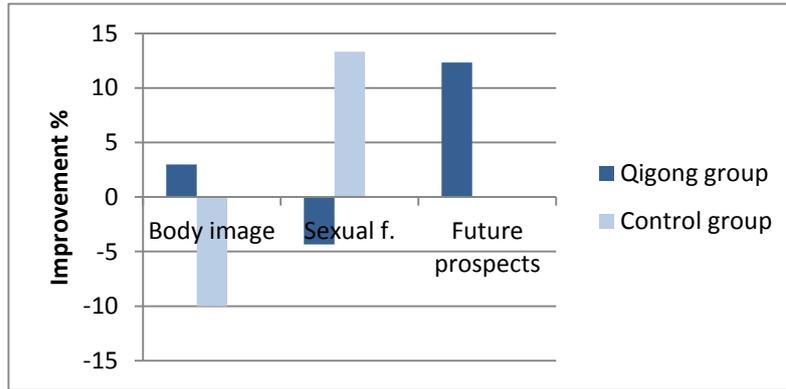


Figure 7 - Comparison of Qigong and Control groups in relation to functional subscales of QLQ Br-23

With regard to symptoms items/subscales, it appears that, in both groups, before and after intervention, symptoms in arm are the most prevalent, being that in control group they aggravate while in qigong group this concern has diminished after intervention.

For less frequent or intense symptoms it appears that, in qigong group, were related to complaints related to the breast, which decreased at the end of the intervention. In the control group before the intervention, the less intense or frequent symptoms were related to systemic effects of therapy, and worsened after the intervention.

In the following figure it can be observe the differences in values found before and after the intervention with qigong (Figure 8).

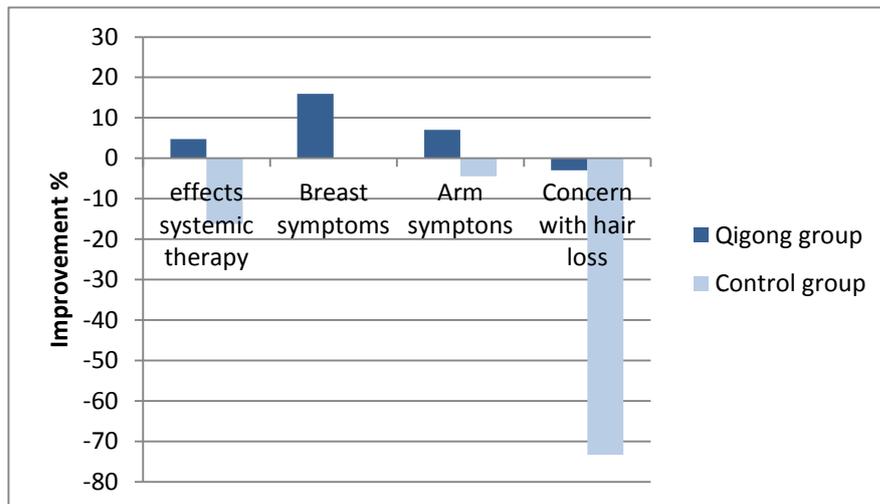


Figure 8 - Comparison of Qigong and Control groups in relation to symptoms subscales of QLQ Br-23

5.4 – Shoulder range of motion on the affected breast side

Below is presented a table for the data obtained in the assessment of shoulder motion on the affected side with respect to flexion and abduction movements, before and after the qigong intervention, in both groups (Table 11).

	Before Qigong				After Qigong			
	Flexion		Abduction		Flexion		Abduction	
	Left	Right	Left	Right	Left	Right	Left	Right
Qigong								
1	---	140	---	110	---	136	---	110
2	120	---	110	---	140	---	116	---
3	---	164	---	170	---	168	---	176
4	100	---	90	---	140	---	160	---
5*	132	144	92	96	140	146	100	120
6	102	---	110	---	140	---	120	---
7	110	---	90	---	140	---	126	---
8*	130	142	80	123	142	148	90	136
9	92	---	84	---	142	---	126	---
10	130	---	90	---	142	---	112	---
11	120	---	102	---	140	---	122	---
Control								
1	120	---	125	---	130	---	128	---
2	132	140	126	138	124	136	122	138
3	90	---	45	---	94	---	42	---
4	90	---	98	---	90	---	96	---
5	---	122	---	142	---	128	---	120

Table 11 – Shoulder range of motion on the affected breast side

*Patients with both breasts affected

Regarding the mobility of the shoulder(s) on the affected breast side, was found that, in qigong group, regarding flexion and abduction movement, 90,9% (n=10) of the sample improved range of motion, being that 9,1% worsened flexion movement and another 9,1% maintained the same movement degree.

In control group, it was found that, in relation to flexion movement, 60% (n=3) of cases have improved range motion, and in 20% (n=1) there was worsening or remained the same amplitude. Regarding the abduction movement in the same group, it was found that, in 80% (n=4) of the cases was an aggravation of the range of motion and only 20% (n=1) remain the extent improved.

The figure below shows the values obtained by the difference between the values, before and after the intervention with Qigong, in order to better visualize the results (Figure 9).

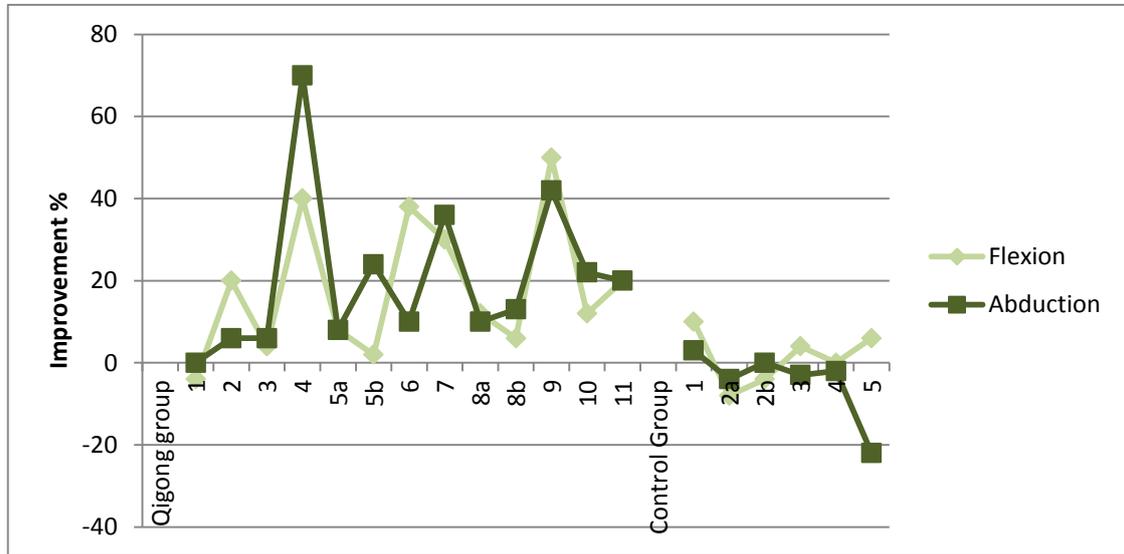


Figure 9 - Comparison of Qigong and Control groups in relation to shoulder range of motion on the affected breast side

5.5. – Salivary cortisol levels characterization

Below is a table relating to the values obtained from the analysis of salivary cortisol before and after the intervention with qigong, in both groups (Table 12).

	Before Qigong	After Qigong
Qigong group		
1	0,521	*---
2	0,534	0,25
3	0,283	0,285
4	0,324	0,318
5	0,152	0,146
6	0,928	0,15
7	0,178	0,165
8	0,314	0,307
9	0,221	0,47
10	0,17	0,119
11	0,312	*---
Control group		
1	0,3	0,186
2	0,238	0,236
3	0,236	0,232
4	0,180	0,183
5	0,184	0,191

Table 12 – Salivary cortisol levels

*It was not possible to determine cortisol level because sample was insufficient

Note - Normal values of laboratory for salivary cortisol in the morning = 0,0-0,650 ug/dl

The picture below shows the values obtained by the difference between the values, before and after the intervention with Qigong, in order to better visualize the results (Figure 10).

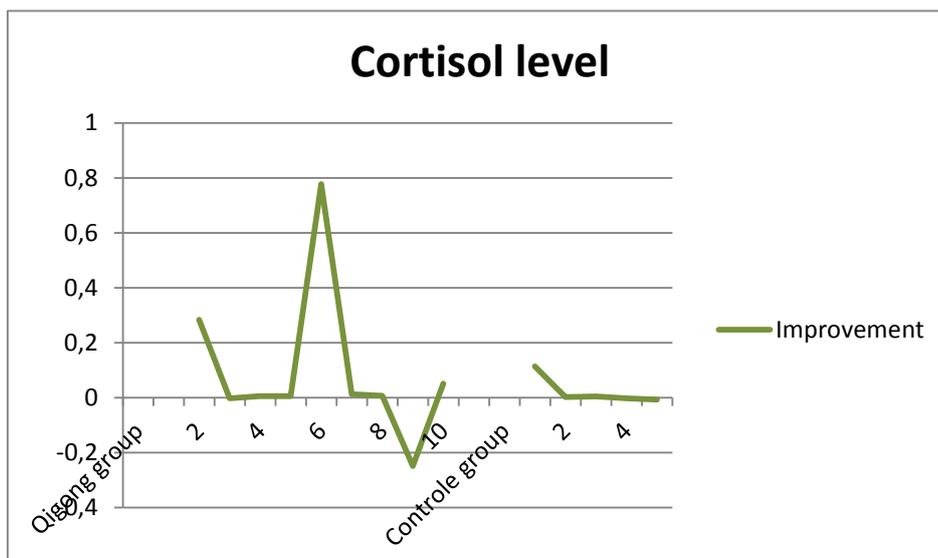


Figure 10 - Comparison of Qigong and Control group in relation to salivary cortisol levels

It was found that, in *Qigong* group, 54,5% of sample decreased levels of cortisol while in the control group was 60%.

6 – STATISTICAL ANALYSIS

The results obtained were also analyzed to observe if their decreasing or increasing were statistically significant. It was done using SPSS.

It was used a non-parametric test; this tests of hypotheses do not require assumptions about the form of underlying distribution of data (Fortin, 1996). It is used when the sample is too small, as is the case of the present study; usually require few assumptions about the data and may be more relevant to a particular practical situation.

In analyzing the results we used the Wilcoxon test; is an alternative to the nonparametric t test for comparison of the mean or average in paired samples. μ represents the median instead of average (Fortin, 1996).

The hypotheses to test are:

H0: The values to test are similar $\mu_1 = \mu_2$

H1: The values to test are different $\mu_1 \neq \mu_2$

The α chosen is 0,05.

We compared the values for each group separately (the group of Qigong and Control) for differences between the assessment before and after the intervention.

QLQ C-30 questionnaire

	Qigong group (<i>p</i> value)	Control group (<i>p</i> value)
Physical functioning	0,426	0,457
Occupational functioning	0,511	0,157
Emotional functioning	0,224	0,064
Cognitive functioning	0,046	0,317
Social functioning	0,782	0,237
Fatigue	0,17	0,072
Nausea and vomiting	0,106	0,035
Pain	0,649	0,054
Dyspnea	0,102	1
Insomnia	0,058	0,317
Loss of appetite	0,931	0,083
Constipation	0,157	1
Diarrhea	0,317	0,317
Financial difficulties	0,414	0,157
Global state of health	0,755	0,046

Table 13- Results obtained from Wilcoxin test for QLQ C-30 questionnaire

In relation to qigong group, it was concluded that the probative value for cognitive functioning are < 0.05 , i.e., rejecting the H_0 , then there are significant differences between the results obtained before and after the treatment. In all other items the probative value was $> 0,05$, so there are no significant differences between the results obtained before and after treatment.

Referring to control group, it was concluded that in symptoms such nausea, vomiting and pain as well as for general health state the probative value was $<0,05$, rejecting the H_0 , so there were significant differences between the results obtained before and after the treatment. In all other items the probative value was $> 0,05$, so there are no significant differences between the results obtained before and after treatment.

QLQ Br-23 questionnaire

	Qigong group (<i>p</i> value)	Control group (<i>p</i> value)
Body image	0,623	0,526
Sexual functioning	0,827	0,157
Sexual pleasure	0,380	0,109
Future perspectives	0,046	1
Systemic effects of therapy	0,260	0,309
Breast symptoms	0,079	0,658
Arm symptoms	0,224	0,719
Loss of hair concern	0,131	0,046

Table 14 - Results obtained from Wilcoxin test for QLQ Br-23 questionnaire

In relation to qigong group, it was concluded that the probative value for future perspectives are < 0.05 , i.e., rejecting the H_0 , then there are significant differences between the results obtained before and after the treatment. While in Control group this was true for loss of hair concern.

In all other items, in both groups, the probative value was $> 0,05$, so there are no significant differences between the results obtained before and after treatment.

Shoulder range of motion on the affected breast side

	Qigong group				Control Group			
	Flexion		Abduction		Flexion		Abduction	
	Right	Left	Right	Left	Right	Left	Right	Left
<i>P</i> value	0,357	0,008	0,109	0,008	0,655	0,593	0,317	0,357

Table 15 - Results obtained from Wilcoxin test for flexion and abduction movement of shoulder

In relation to qigong group, it was concluded that the probative value for the right flexion and abduction movements are > 0.05 , i.e., does not reject H_0 , so there are no significant differences between the results obtained before and after treatment. With regard to the movement of left flexion and abduction, there is evidence that the values are < 0.05 , rejecting the H_0 , then there are significant differences between the results obtained before and after treatment.

Regarding the control group, the results obtained for the flexion and abduction movement (right and left) are not statistically significant.

Salivary cortisol levels

	Qigong group	Control Group
<i>P</i> value	0,086	0,686

Table 16 - Results obtained from Wilcoxin test for salivary cortisol levels

As *P* value is superior to α we can't accept H_0 . This means that cortisol values aren't statistically significant both in qigong or control Group.

7 - DISCUSSION OF RESULTS

Breast cancer is one of the various pathologies that harms psychologically and physically a woman. At the same time, after confirming presence of cancer disease, it unveils some emotions, feelings and behaviours most of the time associated to death.

The main purpose of this study is the objective and subjective assessment of Qigong related effects in breast cancer patients and to contribute to the promotion of efficient interventions, in an integrative perspective. This study was accomplished with two groups, “Qigong” and “Control”, in order to evaluate several parameters such as the efficacy of qigong practice on QoL, the range of shoulder movement of the affected side and the level of salivary cortisol. It should be emphasized that the theoretical framework supporting the methodology and the result discussion is fundamentally related to neurovegetative biofeedback mechanisms according to the Heidelberg model.

Socio-demographic variables

In order to better identification of women in the sample, it is essential to understand the variables that may promote or, conversely, compromising QoL throughout the disease process and on the other hand the influence of qigong practice, although in this study was not possible to establish such relationships due to small sample size, so it can be understood as a preliminary study in this area.

The results showed that, the majority of the qigong group have between 39-59 years old (72,7%), are married (54,4%), have between 7th and 12th grade of educational level (54,6%) and are already retired (54,5%). Regarding control group patients, the majority also have between 39-59 years old (80%), also married (80%), but with lower educational level – between 1st and 4th grade (40%), and 40% are currently employed and others 40% unemployed. In both groups, female gender is dominant.

According to Cimprich (2002), age seems to be a prevalent factor when assessing QoL because younger survivor patients seem to have more difficulties to adjust their quality of life than the eldest. Other studies, as King (2000) and Vacek (2003), corroborate this same idea. Regarding the variable of educational level, Silva et al (2011) states that, a higher educational level and the use of “Active-Cognitive coping” strategies are associated to better global and psychological QoL after diagnosis and during treatment in cancer patients.

Marital status and family unit constitution are variables that might have same influence on results, considering the family support each one can have. Fialho and Silva (1993) emphasized that after mastectomy intervention, women with no familiar support developed more issues at bio-psycho-social level. Social and familiar support is a main key to emotional adaptation and well-being, and consequently better QoL. Other studies, namely Cui et al (2004), demonstrate that marital status, specifically, is a determinant socio-demographic factor on QoL of breast cancer survivors.

Clinical variables

When we analyze clinical variables, we noticed that the majority of patients, in both groups, were diagnosed recently (less than a year ago) and, as a result, didn't have any sign of metastasis. All patients were submitted to chemotherapy treatment and breast surgery – the majority in Qigong group did conservative surgery (tumorectomy), while in control group did radical surgery (mastectomy). We also observed a predomination of concomitant diseases in the majority of patients. A study by Moreira et al (2008) concerning QoL and psychosocial adjustment of women with breast cancer in two different stages (diagnosis stage and survival stage), has shown that those who were diagnosed recently had worse results at physical domain and at QoL in general. Regarding chemotherapy treatments, Rebelo (2006) stated that patients in chemotherapy process suffer more side effects and consequently have worse quality of life.

Having in mind the different surgical procedures, some studies didn't find a difference between women submitted to tumorectomy or mastectomy (Dorval et al 1998, Ganz et al 1992). However, Moyer (1997), through meta-analysis, observed that tumorectomy is better for patient self-esteem and at psycho, social and sexual level. Also, patient is less anxious and has less probability to flare-up the disease.

QLQ-C30 evaluation

The results based on QLQ C-30 scale show a better characterization of QoL of breast cancer patients who participated in this study.

Before surgical intervention, we can notice that the highest scores in performance/functioning were at physical level for the Qigong group (76,36) and social level for the control group (93,33). According to Courney & Friedenreich (1997), the physical status of a patient is extremely important because maintaining physical activity during this oncologic process (i.e. treatment and rehab) leads to a feeling of well-being

and satisfaction. Regarding the sociologic level, as stated before, this may have an important contribution to quality of life of these patients.

On the other hand, regarding QoL, is at emotional level that we find the main problem, registering the lowest scores in both groups (57,58 and 71,67 in qigong and control, respectively). The emotional functioning is directly related to the way people face and live their experiences. According to Santos (2006), some studies revealed that these patients normally show low performances at emotional level, which might be associated to the stress experienced. Another study of Osoba et al (2006) revealed that one of the four main effects that a breast cancer patient wants to avoid most is the emotional disorder. This means that a good treatment on this area would increase their quality of life.

According to Rebelo (2007), losing a breast or part of it has an enormous psychological impact and a devastating effect on women. After intervention, we can see that in Qigong group the scores increased for every subscale, especially for emotional functioning. However, in control group, the scores decreased. These results are in accordance with a study of Butow (2010) about the impact of qigong in quality of life, fatigue, humor and inflammation of cancer patients. This study stated that qigong group patients increased more in terms of well-being than control group patients.

The QLQ C30 scale allows us to define some symptoms which can act, directly or indirectly, upon patient's QoL. According to Ribeiro (2003), the good controlling of symptoms is the main difference between having good or poor quality of life. Thus, and taking into account the results obtained, they showed that, before the intervention, in both groups, the symptoms more intense or more present, were insomnia and fatigue. These results are similar to those obtained by Bernardo (1997) who found that in 50% of patients undergoing chemotherapy they reported fatigue experience. Studies have even indicated that fatigue is not only felt during the treatment but persist for several years (Chantal 2001). Also Lindley et al (1998) evaluated the quality of life of 86 women who underwent adjuvant therapy verifying that fatigue and insomnia were some of the most common symptoms. Nevertheless, in qigong group was an improvement of this symptom after the intervention, while the same was not observed in the control group. Also according Butow (2010), qigong group participants had significant improvements in scores for fatigue. Sun and Zhao (1988), in a study conducted with 123 cancer patients found that the qigong group, 82% of patients had regained strength. However, nausea and vomiting were symptoms with aggravation, after the intervention, in both groups. In the analysis of these results we must take into account that most people who constituted the groups, in the first assessment, were beginning to start chemotherapy treatment, and, as such, did not have present the symptoms before referred.

With regard to health status in general it was found that, in qigong group, it has improved, while in control group decreased, the latter being more significant with regard to QoL in general. The findings provide same evidence for the impact of qigong on QoL in breast cancer patients.

Discussion of QLQ-Br 23 results

In relation to the specific module of quality of life of breast cancer patients, before and after intervention in both groups, we can observe their best performance was at sexual level and body concept was also satisfactory.

The present results are consistent with Santos (2006), which demonstrated that women with breast cancer adopt a strategy of despair or fatalism type in the post diagnosis evolving into an attitude of acceptance of the disease at the same time that the body image of themselves go better. On the other hand, Maker et al (1997), found differing results, indicating that although women in their study consider their quality of life good or excellent, did not feel attractive, and indeed has decreased sexual desire and pleasure. Also a study conducted by Ganz et al (2004), with women diagnosed with breast cancer, has shown that the scale of sexual functioning is worse in the group of women receiving chemotherapy.

Regarding the future prospects of life were obtained very low scores, indicative of his constant preoccupation with the fear of disease recurrence.

To what comes to regularity/intensity of symptoms, it were symptoms related to affected side arm the most relevant. After intervention, it improved for Qigong group, which meets the results obtained on this work.

Assessment of shoulder movement range

This work detected breast cancer patients have articular limitations, especially on affected side. According to a study conducted by Silva (2009), 98,2% of breast cancer women had some kind of limitation on affected side after surgery.

According to our data, shoulder flexion and abduction of the affected breast side, measured by goniometry techniques, showed higher improvement in qigong group than in control group. So, after this analysis, we can affirm that in this preliminary study qigong was determining on this matter.

Salivary cortisol levels

Effectively, same studies indicate that qigong may have health benefits such as decreased levels of circulating stress hormones, like cortisol (Ryu et al, 1996). Jones (2001) did also a study to investigate the changes in cytokine production, blood pressure, pulse rate, blood cortisol level in healthy subjects that practicing Guolin qigong daily over 14 weeks. This preliminary study has indicated that blood levels of the stress-related hormone cortisol may be lowered by short-term practice of qigong and that there are concomitant changes in numbers of cytokine-secreting cells.

Lee et al (2004) study the effects of qigong on anxiety, and plasma concentrations of adrenocorticotrophic hormone (ACTH), cortisol, and aldosterone in healthy young men assigned to a control group or a qigong group. They observe that anxiety decreased by 26% in the qigong group and by 9% in the control group, and also, the plasma concentrations of ACTH, cortisol, and aldosterone decreased, but these levels did not change in the control group. These findings suggest that qigong may improve anxiety and may have a significant effect on the hypothalamic–pituitary–adrenal axis.

Our present results, from the analysis of cortisol levels, in both groups, before and after the intervention with qigong, showed that, values in general decreased in both groups, this decrease being actually more evident in the group of qigong. So, according the mentioned literature, these results may suggest that qigong has a significant effect at the concentration of salivary cortisol, which may possibly reflect greater stability in the levels of stress. This is according the TCM Heidelberg model informs that the biofeedback effect of qigong direct and mainly influence the neurovegetative system which supports the most aspects related with anxiety and stress conditions.

8 - CONCLUSION

Bearing in mind the objectives that guided this research, were identified the main conclusions, in line with the objectives we set ourselves and the study's purposes, which were to objective and subjective assess the qigong related effects breast cancer patients. As was being discussed throughout the work, the breast cancer disease is one of the most feared by women, constituting a major cause of death, been also considered a chronic degenerative disease with major implications at bio-psycho-social level.

The concept and existence of Qi has been a challenge for modern medicine and science in general, since it is difficult to measure. However, much evidence suggests that qigong therapy may have therapeutic effects on cancer suggesting a potential alternative for cancer treatment.

Thus, with the present preliminary study we propose that this therapy should be seriously examined and considered as an important supplement to conventional treatment of cancer, specifically in the breast cancer patients, even when practiced over a short period of time. Although the results are positive and promising, there are some limitations to the study and methodological approach that should be taken into account when interpreting the results.

To carry out a research always involves limitations related to several factors that are revealed during the travel. Effectively, it is pertinent to mention some of the limitations to this study, being some of them related to the fact that the two groups constituting the sample did not have the same number of elements and encompassed a small number of individuals. On the other hand, the sampling method used, a convenience sample, may have created some pre-selection. Effectively, participation in the present study was voluntary and that may have created a potential selection bias, with those patients interested in qigong participating and, those with no interest in qigong declining. This may limit the generalization of the findings, but does not invalidate the results for this specific sample. Contrary to recommendations for drug trials, it was not possible to make use of a blinding protocol, due to the nature of the intervention. So neither the participants nor the instructor were blind to condition.

Also the inclusion of the control group receiving usual care may indicate that the significant results may have been due to the additional attention received rather than the intervention. For the same reason, it was felt appropriate to use more objective assessment tools, such as the evaluation of salivary cortisol levels, and interpretation of

results comparing each group individually, the data obtained before and after the intervention, rather than compare the two groups together.

Given the difficulties to objectively assess qigong effects, the study shows that the combination of subjective scores with objective assessment of cortisol levels and physical parameters may show new possibilities to do qigong research on a higher quality level by objective assessments.

Thus, in future studies, it seems essential to seek to overcome these limitations and contribute to a more profound contribution to the understanding of qigong therapy in breast cancer. It would be interesting to investigate the phenomenon in more depth and over a longer period of time. This might also influence the statistical power of the study.

***Those who pass us by,
Do not go alone
Do not leave us alone.
They leave a little of herself,
Take a few of us.***

Antoine de Saint Exupéry

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Annexes

Annex I - Authorization request

Annex II – Permission obtained

Annex III – Socio-demographic Questionnaire

Annex IV - Clinical data characterization

Annex V – QLQ C-30 / Br-23

Annex VI – Informed Consent