AMERICAN UNIVERSITY OF BEIRUT

PREVALENCE AND DETERMINANTS OF THE USE OF COMPLEMENTARY AND ALTERNATIVE MEDICINE AMONG BREAST CANCER PATIENTS IN LEBANON

by
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AN ABSTRACT OF THE THESIS OF

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Title: Prevalence and Determinants of the use of Complementary and Alternative Medicine among Breast Cancer Patients in Lebanon.

The objective of this study is to assess the prevalence and determinants of CAM use among breast cancer patients in Beirut, Lebanon. A cross-sectional survey was conducted on 180 breast cancer patients recruited from two major referral centers in Beirut. In a face to face interview, participants completed a questionnaire comprised of three sections: socio-demographic and lifestyle characteristics, breast cancer condition, and CAM use. Prevalence of CAM use since diagnosis was 40%. CAM use was negatively associated with age, treatment at a philanthropic hospital and positively associated with having an advanced stage of disease. The most commonly used CAM was 'Special food' followed by 'Herbal teas'. Only 4% of CAM users cited health care professionals as influencing their choice of CAM. One in four patients disclosed CAM use to their treating physician. The use of CAM therapies among breast cancer patients is prevalent in Lebanon. Efforts should be dedicated at educating physicians to discuss CAM use with their patients and advising patients to disclose of their use with their physicians.

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ABBREVIATIONS

AUB	American University of Beirut
CITI	Collaborative Institutional Training Initiative
CAM	Complementary and Alternative Therapy
CI	Confidence Interval
=	Equal To
€	Euro Currency
GP	General Practitioner
>	Greater Than
≤	Greater than or Equal To
IRB	Institutional Review Board
<	Less Than
≥	Less Than or Equal To
MGH	Makassed General Hospital
MoH	Ministry of Health
NCCAM	National Center of Complementary and Alternative Medicine
NHIS	National Health Interview Survey
n	number
OR	Odds Ratio
/	Per
%	Per Cent
±	Plus or Minus
£	Pound Currency
p	P-value

RCT	Randomized Controlled Trials
SD	Standard Deviation
TAIM	Traditional Arabic and Islamic Medicine
TCM	Traditional Chinese Medicine
$	United State Dollar
USA	United States of America
WHO	World Health Organization

To My

Beloved Family

CHAPTER I

LITERATURE REVIEW

A. Breast Cancer

Global cancer burden increased from 2008 to 2012.The increase was from 12.7 million to 14.1 million new cases and from 7.6 million to 8.2 million cancer deaths respectively (International Agency for Research on Cancer 2013). Cancer is triggered by an alteration in the cells of the body where they become modified and out of control. Majority of cancers from a lump or a mass, that is commonly known as a tumor and is usually named after the body part where the mass was initially formed. Breast cancer begins in breast tissues and is usually identified by different examination methods varying from simple clinical assessments to microscopic analysis via a biopsy (American Cancer Society 2011). There is also a marked increase in breast cancer worldwide (Ferlay, Héry, Autier and Sankaranarayanan 2010). Breast cancer is the most common cancer among women in both developed and the developing world (WHO 2014).

1. Prevalence of Breast Cancer

a. Prevalence in the World

Although breast cancer is thought to be a disease of the developed world, almost 50% of breast cancer cases and 58% of deaths occur in less developed countries (Ferlay *et al*. 2010). Breast cancer (1.7 million, 11.9%) is ranked second by cancer occurrence in both genders in the most common diagnosed cancers worldwide after lung cancer (1.8 million, 13.0%). In 2012, 1.7 million women were diagnosed with breast

cancer moreover there were 6.3 million women alive who had been diagnosed with breast cancer in the previous 5 years (International Agency for Research on Cancer 2013).

Incidence rates vary widely worldwide from 19.3 per 100,000 women in Eastern Africa to 89.7 per 100,000 women in Western Europe (WHO 2013).

Moreover the incidence increased from the year 2008 by over 20% and mortality by 14%. It has become the most frequent diagnosed cancer among women in 140 of 184 countries worldwide and now has become 1 in 4 of all cancers among women (International Agency for Research on Cancer 2013). Breast cancer is one of the most common causes of cancer death among women world-wide, It was estimated that in 2011 more than 508,000 women worldwide died from breast cancer (Global Health Estimates, WHO 2013).

Incidence rates are still the highest in more developed areas however mortality is somewhat much higher in less developed countries due to lower access to treatment facilities and lack of early detections and diagnosis. In Western Europe, breast cancer incidence among women is almost 90 new cases per 100,000 yearly as compared to a lower incidence in eastern Africa 30 per 100,000. On the other hand, mortality rates in these two regions are almost alike and account to 15 per 100,000 this refers to a later detection and poorer survival in eastern Africa (International Agency for Research on Cancer 2013).

The incidence is increasing in the developing world due to several reasons such as the increase of life expectancy, urbanization and westernization (WHO 2013).

The estimated predictions of breast cancer cases for the year 2030 in the different regions of the world are expected to increase by 2.7 million new cases worldwide. At the same time, having more than 60% of those cases, 1.72 million,

occurring in less developed countries. These estimates assume current rates remaining and increasing constantly (Ferlay *et al*. 2010).

b. Prevalence in the Region

Breast cancer is also the most common diagnosed cancer among women in the four member countries of the Middle East Cancer Consortium; they are Cyprus, Egypt, Jordan and Israel. The results of a study done in 2006 showed that, Jordan had the least cancer cases (113·3 cases per 100 000), however Israeli Jews (274·4). The rate in Cyprus was (164·2), Israeli Arabs (149·8), and Egypt "Gharbiah region" (143·0) (Freedman, Edwards, Ries and Young 2006).

Another study done in 2010 reviewed national data on breast cancer and categorized the regional countries according to diagnosis of breast cancer as a proportion of all types of cancer among women. Lebanon coming first (2004) with 38.2% of female breast cancer of all cancer among women followed by Egypt in the years (1999-2001)with 37.6%, Jordan in 2005 accounted for 36.2% and the least was documented in Saudi Arabia in 2004 by being 22.4% (Lakkis, Adib, Osman, Musharafieh and Hamadeh 2010).

c. Prevalence in Lebanon

Lebanon is a small country located on the Eastern shore of the Mediterranean Sea with a population of around 3.3 million people. Cancer incidence rates were lacking for decades due to many reasons particularly the political instability and the civil war that took place through the years 1975 to 1991. The only study published in estimating the incidence rate was back in 1966. Later many attempts were done in establishing estimates for the incidence rate of cancer in Lebanon. In 1989, a study was

done based on the first national database cancer incidence postwar period it included 4388 new cases of patients diagnosed with cancer out of those cases 47.7 % were among females and the most frequent reported type of cancer was breast cancer. It constituted to almost one third of all cancers in Lebanon (Shamseddine *et al*. 2004).

Among Lebanese women diagnosed with cancer, breast cancer accounted for 29.2 % in 2002, 42.3 % in 2003 and 38.2% in 2004 (Shamseddine and Musallam 2010). The incidence of breast cancer among women in Lebanon occurs at a younger age compared to the West (Lakkis *et al*. 2010). This percentage (38.2%) is higher than that reported in the regional and Western countries. A recent study conducted (2003-2008) in Lebanon showed persistent results and that breast cancer remained the most common cancer among Lebanese women with an increase in age-standardized incidence rate from 78.3 (2003) to 95.7 (2008) cases per 100,000 (Shamseddine *et al*. 2014). The Median age at diagnosis in Lebanon is 52.5 years (El Saghir *et al*. 2006; Lakkis *et al*. 2010). This estimated rate was lower than the rate in developed regions and among the Israeli Jewish population (Tarabeia *et al*. 2007). However comparing this rate with the regional Arab countries it was even greater. The median age of diagnosis in Lebanon for the years 1989 and 2004 was around 52 which is comparable to some Arab countries especially Jordan 53.5. On the other hand the median age of diagnosis was even lower in some regional countries such as Saudi Arabia 47.0 in 2004, Kuwait 45.0 in 1993 towards 1998 and Egypt 46.0 in 2001. However comparing the median age to the developed countries, Lebanon had almost a 10 year younger age of diagnosis as compared to USA which was 61 in 2001 towards 2005 and 63 years in Western Europe (El Saghir *et al*. 2007).

2. Risk Factors

Some of the unmodifiable risk factors for breast cancer are as follow: age, family history, early menarche and late menopause. However there are other modifiable risk factors that might lead to an increased risk for breast cancer such as postmenopausal obesity, the use of combined hormone therapy, excessive alcohol consumption and physical inactivity (American Cancer Society 2011).

Even after adjusting for the modifiable risk factors, women cannot eliminate the majority of breast cancers. Unfortunately it cannot be prevented, and the critical point and foundation of breast cancer is early detection, regular mammograms are advisable, for early detection in order to improve the outcome and survival (Elobaid, Aw, Grivna and Nagelkerke 2014).

3. Management and Treatment of Breast Cancer

Treatment of breast cancer varies from a patient to another and varies with different staging of the disease, patients' age and preference. However most breast cancer patients undergo surgery that is combined with another mode of treatment such as chemotherapy, radiation and hormone therapy (American Cancer Society 2011). Modified radical mastectomy (MRM) is the most common operation in the treatment of breast cancer among Arab women. Chemotherapy and radiation therapy remain a necessary procedure as well in the journey of treatment in breast cancer patients (El Saghir *et al*. 2007).

In Recent years, medicine has witnessed remarkable advances in the treatment and management of breast cancer. With these medical advancements, the survival rates for women diagnosed with breast cancer increased and became 89%, 82%, 77% at 5 years 10 years and 15 years from diagnosis (American Cancer Society 2011).

However patients suffering from cancer experience numerous distressing physical and psychological symptoms either due to their cancer or as an adverse side-effect of the treatment of their cancer. The different treatment methods are commonly accompanied with a range of mild to severe temporary and sometimes chronic life-threatening symptoms. In a systematic review of 46 studies, the five most common symptoms reported by 50% of cancer patients were pain, fatigue, weakness, lack of energy and the loss of their appetite (Teunissen *et al*. 2007).

In a study done in Lebanon targeted to determine symptom prevalence and management in patients with cancer, had similar result to the review above. Scoring the highest symptom among many oncology patients was the lack of energy 63% followed by nervousness 54.4% and feeling sad 50.5% (Huijer, Abboud and Doumit 2012).

In addition to conventional therapies for breast cancer, women get involved in proactive steps assuming they will positively influence their prognosis after diagnosis. Such steps include adapting some lifestyle changes and the use of complementary and alternative medicine (Greenlee *et al*. 2009). Despite the advancement in the conventional medical treatment for these patients, numerous side effects are associated with it and many challenges face cancer patients such as the high cost and sometimes in availability of the treatments. Side effects of cancer treatment are of major concern and are associated with stress in cancer patients (Buettner *et al*. 2006; Fox *et al*. 2013).Moreover, major breast cancer patients in developing countries are being diagnosed at an advanced stage of the disease. They reach a point where conventional medical treatment is of little help (Fox *et al*. 2013). The dissatisfaction skepticism and many times the lack of conventional cancer treatments were suggested to drive a considerable proportion of patients to seek and explore alternative modalities for treatment of their disease ; known as complementary and alternative medicine (CAM).

Recently, other factors have emerged and are additional contributing factors that result breast cancer patients in resorting to CAM use. These contributing factors are primarily associated in enhancing the patient's psychological and spiritual wellbeing. Patients often resort to active coping with the disease, they tend to seek information, make diet and lifestyle modifications, increase available social support and acquiring strategies targeted to decrease stress. All these, were found to improve emotional and physical well-being nonetheless the patients quality of life (Cheng e*t al*. 2012; Shapiro, McCue, Heyman, Dey and Haller 2010).

It is suggested that using CAM among cancer patients and more specifically breast cancer patients may be done to satisfy an important physiological need. Furthermore, allowing patients to be actively involved in the process of therapy and to retain personal control over their illness (Moschèn *et al*. 2001).

B. Complementary and Alternative Medicine (CAM) Use among Breast Cancer Patients

1. Definition

Terms not commonly included in mainstream-conventional medicine have continuously transformed over the time evolving from the very negative "quackery" term to "unorthodox", "unconventional", "questionable", "unproven" and "alternative". Current however still changing terminology; favors "complementary" and "alternative" medicine (Cassileth & Deng, 2004). According to the National Center for Complementary and Alternative Medicine (NCCAM), which is the Federal Government's lead agency for scientific research on complementary and alternative medicine (CAM) there are numerous definitions to CAM and of those none is perfect. They define it as "a group of diverse medical and health care interventions, practices,

products, or disciplines that are not generally considered part of conventional medicine." This definition will be applied for the purpose of this thesis. The boundaries between CAM and conventional medicine which is also termed as the Western medicine are not absolute. CAM interventions are frequently practiced in integrative medicine practices in conventional medical care settings. Data from national surveys suggest that "CAM is often used as a complement or adjunct to conventional medical care." NCCAM also defines complementary medicine as being "used together with conventional medicine" and alternative medicine as being "used in place of conventional medicine" (American national center for complementary and alternative medicine, national institutes of health 2007; NCCAM 1992; Plan 2011). Complementary therapies are used as adjuncts to the mainstream cancer care where they act as supportive measures in controlling symptoms, enhancing the wellbeing and contributing to the overall patient care (Cassileth and Deng 2004).

a. Classification of CAM

NCCAM classifies CAM therapies into five categories. The first being alternative medical systems and examples of such systems developed in the Western cultures are homeopathic medicine and naturopathic medicine. Moreover examples developed in non-Western cultures include Chinese medicine and Ayurveda. The second category is the mind-body interventions that include patient support groups, cognitive-behavioral therapy, meditation, prayer, mental healing and therapies that use creative outlets such as art, music and dance. The third category is entitled biological based therapies in CAM and these use substances found in nature. Examples of the following are herbs, foods and vitamins such as dietary supplements. The fourth category is the manipulative and body-based methods in CAM that involve the

manipulation and/or movement of different parts of the body and include chiropractic or osteopathic manipulation and massage therapy. The final category classified was energy therapies and involved the use of energy and further divided into two subgroups. The first subgroup is the biofield therapies such as qi gong, reiki and Theraputic Touch. The second being bioelectromagnetic-based therapies that revolve around the use of electromagnetic fields such as pulsed fields or alternating-current field (American national center for complementary and alternative medicine, national institutes of health 2007).

2. Prevalence and Cost

a. Worldwide

The National Center for Health Statistics at the Center of Disease Control and Prevention did two National Health Interview Surveys (NHIS) in the years 2002 and 2007. These surveys evaluated the use of CAM among the adult American population and estimated it to be around 40 percent which is about 4 in 10. Another finding was that Americans were reported spending $33.9 billion out-of-pocket for different CAM therapies in 2007 (Plan 2011). The use of CAM among cancer patients is widespread and seems to be increasing in many parts of the worlds. Recently the literature has documented a relatively high prevalence of CAM use among cancer patients in general and breast cancer patients in particular (Fox *et al*., 2013; Tautz, Momm, Hasenburg and Guethlin 2012). A European survey concluded that the range of CAM use among cancer patients in 14 different countries was between 14.8% - 73.1% (Molassiotis *et al*. 2005).Moreover it is becoming one of the fastest growing treatment methods in the United States (Nahleh and Tabbara 2003).

Moreover women with breast cancer are more likely to engage in CAM use

compared to other oncology patients (Alferi, Antoni, Ironson, Kilbourn and Carver 2001). A review done between the years 1975 to 2002 showed that the range for CAM use in breast cancer patients was between 48% and 70% in the United States (Nahleh and Tabbara 2003). Another study an ongoing prospective cohort study done on Kaiser Permanente Northern California Members showed that most women (96.5%) reported a history of at least one form of CAM use (Greenlee *et al*. 2009).

A study done in Australia that included 367 breast cancer patient revealed that among those 87.5 % had used CAM therapies with many of them using four or even more therapies together (Kremser *et al*. 2008).

The prevalence and pattern of CAM use is correlated to socio-demographic factors, ethnicity and the health care system (Lee, Lin, Wrensch, Adler and Eisenberg 2000). Similar to the previous studies, CAM use among breast cancer patients is also prevalent in Ireland, an Irish study revealed that over half (55.7%) of breast cancer patients involved in the study used CAM since diagnosis (Fox *et al*. 2013).

In addition to those, a UK-population based survey showed that 31.5% of women with breast cancer used a CAM therapy after their diagnosis taking into consideration the authors' opinion that this number was underestimated. That study also revealed that around £17,000 was spent among those patients in the previous year on CAM therapies (Rees *et al*. 2000).

A more recent study on 2562 breast cancer survivors revealed that around 80% used CAM therapies for general purposes and 50% resorted to CAM for their cancer purposes (Saquib *et al*. 2011).

In a study that is part of a bigger study done in Europe on 126 breast cancer patient, CAM's average cost per participant was estimated to be € 88.5 per month. Nevertheless, countries with higher purchasing power standards spent more than that

number on different CAM modalities (Molassiotis *et al.* 2006).

b. Regional

A cross-sectional study done in Iran on women with breast cancer, 32% of the patients reported that they have-used or are using some sort of CAM therapy (Montazeri, Sajadian, Ebrahimi and Akbari 2005).

A study done in Turkey on patients with breast cancer showed that the prevalence of CAM use among those patients was 48.8% (Kurt, Keşkek, Çil, and Canataroğlu).

c. Lebanon

The findings from a study done on diabetic patients and their use of CAM in Lebanon showed that out of 333 participants that were enrolled in this study 38% of those used CAM therapies (Naja *et al*. 2014).

The only study done on the use of CAM among pediatric patients with Leukemia showed that 15.2 % of respondents reported using one or more CAM therapy for their child (Naja, Alameddine, Abboud, Bustami and Al Halaby 2011).

In Lebanon, CAM use is both prevalent and culturally acceptable, and up to this date there is no data on the prevalence and determinants of CAM use among breast cancer patients.

3. CAM Users

Studies done on cancer patients and on the general population all have concluded that people that seek CAM therapies are the more educated, are of higher socioeconomic status, women more than men and are younger than people who don't

use CAM (Ernst 1998). According to the (NHIS) survey in 2007 studying CAM users in the U.S. it showed that CAM use among adults was greater among women and those with higher levels of education and higher incomes. Moreover the most age group involved in CAM use was 50-59 years of age (44.1 %) and when classified into race/ethnicity the majority of CAM users were American Indian/Alaska Native (50.3%) (American National Center for Complementary and Alternative Medicine, National Institutes of Health 2007).

In a systematic review done on breast cancer patients and the use of CAM therapies that included 33 articles (1990-2009), found out that the socio-demographic characteristics associated with CAM use was age, education, income, marital status, health insurance and support group. Out of 29 studies that studied the associations to CAM use, 22 studies revealed that higher association was attributed to younger women and higher education as compared to older women with less education. Also, of the 29 studies, women with higher income used CAM therapies more than women with lower income. Among those studies, 5 studies showed that married women were found to use CAM more than single women (Wanchai, Armer and Stewart 2010).

Consistent findings were also concluded from a German study done on CAM use among breast cancer patients where the predictors for CAM use were among younger age, higher education and advanced clinical stages (Tautz *et al*. 2012).

Also, CAM users among breast cancer patients are "active problem-oriented coping style" where they search for information and try to find solutions for their disease, " religiousness and searching for meaning " by accepting their disease for that was their destiny and resorting to religion for comfort , and a higher tendency to the use of " diversion and self-encouragement" by encouraging themselves and detaching from their disease (Moschèn *et al*. 2001).

Similar to other studies mentioned above, a European study done on 11 countries also showed that the use of CAM among breast cancer patients was higher among younger women (p=0.005), among higher education (p=0.002) also higher income however it was not statistically significant (p=0.077) (Molassiotis *et al.* 2006).

4. Forms of Cam

a. Common CAM Worldwide

From the European survey done on 14 different countries on CAM use among cancer patients, 58 therapies were identified as being commonly used. The following were the majority used; herbal medicines and remedies followed by homeopathy, vitamin/minerals, medicine teas, spiritual therapies and relaxation techniques respectively (Molassiotis *et al*. 2005).

A review done from 1975 till 2002 studied the different CAM modalities used among breast cancer patients. It revealed that the most common CAM used was dietary supplements, mind-body approaches and acupuncture (Nahleh and Tabbara 2003). A study done on the use of CAM therapies among breast cancer patients in an region in Canada showed that 67% of their sample used at least one modality of CAM during their disease period. Moreover the three most common CAM therapies used among those women were meditation/relaxation therapies followed by vitamin/tonics and spiritual/faith healing. Of those women 77% "completely adhered" or "almost adhered" to the CAM treatment used (Balneaves, Kristjanson and Tataryn 1999).

From the Australian study mentioned earlier, on CAM use among Australian women with breast cancer the most commonly used forms of CAM used were vitamin supplements (54.2%), support groups (49.8%), massage (41.4%) and meditation (38.7%) (Kremser *et al*. 2008).

A study done on 2562 breast cancer patients revealed that 50% of the sample used CAM for the purpose of cancer, and that the most common CAM modalities used among them were" mind-body interventions", "body based methods" and an "energy-based therapy". Of those, visual imagery (79.0%), spiritual healing (73.2%), meditation/relaxation (58.7%), naturopathic medicine and chanting/music therapy both (58.5%) and Reiki (51.6%) were the most frequent CAM modalities used among those patients (Saquib *et al*. 2011).

A study done in Germany on CAM use in breast cancer patients concluded that the percentages of CAM modalities among those patients are as follow vitamin/minerals (66%), mistletoe therapy (51%), yoga/relaxation technique (43%), herbal medicine (33%), physical therapies (33%), homeopathy (29%), manual manipulation (14%) and acupuncture (10%) (Tautz *et al*. 2012).

b. Common CAM in the Middle East and in Lebanon

Studies conducted in the regions of Israel, Syria and Palastine have shown that one of the most common CAM used in the treatment of different kinds of cancer is the usage of certain herbs and herbal remedies (Alachkar, Jaddouh, Elsheikh, Bilia and Vincieri 2011; Ali-Shtayeh, Yaniv and Mahajna 2000; Said, Khalil, Fulder and Azaizeh 2002).

In 2002, an ethnopharmacological survey was done among 31 popular Arabic indigenous herbal practitioners in the region of Israel, the Golan Heights and the West Bank. They evaluated the most commonly used local plants in treating different diseases and conditions in that area. 129 plant species are still being used by herbal practitioners in Arabic traditional medicine for treating different diseases. 13 species were being used as decoction for treating cancer such as certain leaves "عشبة الجارات", fruits and bark

"بلوط", stem bark or fruit "سنديان ", shoot "كميه ", foliage "قريص" and "لوف", bulb بصل "الثم", leaf or root "قطلب" and "سدر دوم", whole plant "ملفوف", fruit or flower "زعرور", leaf "غار رند" and kernel and fiber "ذره". All of which can be prepared by boiling them with water and consuming it 3-4 times per day orally or internally as a treatment for cancer (Said *et al*. 2002).

A cross-sectional study done on cancer patients in Jordan on 1138 patients concluded that 35.5% were using botanicals based CAM. The majority used the crude extract in the form of an infusion (73.3%). 6.8% were using the herbs in a dosage form such as "garlic tablets". 19.8% of the participants reported using other individualized herbal preparations from "herbalists" such as "honey mixtures with herbs or herbs soaked in olive oil" (Afifi, Wazaify, Jabr and Treish 2010).

A study done in Iran, showed that "prayer and spiritual healing" was the most frequent form of CAM used among those patients 73.8 % while other modalities used were a lot less common such as "bioenergy" 11.5%, "herbs" and "homeopathy" each 3.3%. However their use of other therapies such as acupuncture, counseling, meditation, yoga was very rare and each only constituted 1.6% of the sample used for this study (Montazeri *et al*., 2005).

The Turkish study mentioned previously also found that the most frequent CAM used among their study population was found to be herbal therapy 98.4% *(Kurt et al*.).

Herbal medicine is generally classified into four basic systems as follows: "Traditional Chinese Herbalism", "Ayurvedic Herbalism", "Western Herbalism" which originated from Greece and Rome then extended to Europe and then spread to North and South America and finally the "Traditional Arabic and Islamic Medicine" (TAIM). Recently this type of CAM, Arabic traditional herbal medicine is being incorporated in

the modern life in the Middle East as well as gaining worldwide popularity and growth among traditional herbalists and some scientific communities. TAIM therapies have shown remarkable success in healing diseases such as cancer and are being used by people in different parts of the world especially the Mediterranean whom have faith in spiritual healers (Azaizeh, Saad, Cooper and Said 2010).

The most common type of CAM used among pediatric patients with Leukemia in Lebanon was dietary supplements such as blackseed (28.5%) or honey and carob syrup mixture (4.7%), prayer/spiritual healing (28.6) and unconventional cultural practices such as ingesting bone ashes (19%) (Naja *et al*., 2011).

5. Reasons for CAM Use among Breast Cancer Patients

The European survey done on CAM use among cancer patients showed that the main drive for patients to resort to CAM was to "increase their body's ability to fight the disease" (50.7%), to "improve physical well-being" (40.6%) and "improve emotional wellbeing (35.2%). However the experienced benefits towards CAM use in those patients showed that only (22.4%) of the CAM users that took CAM to fight the cancer found it to be useful ; on the other hand a higher percentage (42.5%) found CAM to improve emotional wellbeing (Molassiotis *et al.* 2005).

A study done in Ontario, Canada on 411 patients with breast cancer stated that there are many reasons behind their CAM use. Of which were boosting the immune system (63%), improving the quality of life (53%), preventing the recurrence of cancer (42.5%), proving control over life (37.9%), treating breast cancer (27.9%), for the side effects common with the conventional treatment (21%), trying to stabilize their existing condition (17.4%) and finally to compensate for failed conventional treatment (5%) (Boon *et al*. 2000).

Another study in Australia showed that some common reasons for CAM use among women with breast cancer were to improve their physical (86.3%), emotional (83.2%) wellbeing and very similar to the previous study to boost the immune system (68.8%). 39.9 % of the participants reported using CAM therapies in order to prevent breast cancer reoccurrence, 38.6% to help in treating their cancer and 35.5% in reducing the symptoms associated with breast cancer. About half of the participants used CAM to reduce the treatment side effects (49.2%) (Kremser *et al*. 2008).

Another study done in Austria on breast cancer patients and the use of CAM therapies showed that the main reasons for their tendency for CAM were having "an active role in treatment" (47%), their desire "to leave nothing untried" (47%), to "complement conventional treatment" (31%) and their wish to have "a gentle treatment free" or for the "adverse effects" (18%). Moreover other reasons also include "strengthening of the immune system" (82%), "improvement of the general state of health" (53%) and finally the "prevention of relapse" (27%) (Moschèn *et al*. 2001).

The most common reasons that resorted in CAM use among pediatric Leukemia patients in Lebanon was "strengthening the immunity" (42.1%) followed by "improving the chance of cure" (21%), "detoxification" (10%), "minimizing the pain" (11%), "lack of trust in conventional medicine" (11%) and finally the belief that "CAM stops the progression of the disease" (5%) (Naja *et al*. 2011).

6. Safety and Effectiveness of CAM and Breast Cancer

Several studies evaluated the effectiveness of some CAM therapies among breast cancer patients. Many symptoms accompanying breast cancer is limited however growing. There are some evidences in the literature from different RCTs that demonstrate the effectiveness of certain CAM therapies in treating different symptoms

that accompany breast cancer patients. For example for treating fatigue most commonly used CAM proven to be effective was physical exercise and acupuncture. For the treatment of hot flashes and arthralgias also acupuncture was the most evident CAM for. Insomnia was treated by cognitive behavioral therapy (Blaes, Kreitzer, Torkelson and Haddad 2011).

There are some evidences that support the use of some CAM modalities when used in addition to the standard cancer treatment (Hardy 2008; Murphy *et al*. 2011; Sakamoto *et al*. 2006).

In tested double-blinded, placebo-controlled clinical trials, CAM therapies that's intended to treat cancer alone, showed no benefit (Balneaves *et al*. 1999; US National Institutes of Health 1995). However, there are some evidence that support the use of certain oral CAM therapies such as Ginger, probiotics/yoghurt and fish oil supplement. Each to treat a specific cancer related symptom. For example, ginger "significantly decreased chemotherapy-related nausea when compared with a placebo". On the other hand, probiotics/yoghurt "reduced fluorouracil chemotherapy-related diarrhea" (however there was a case of death in a non-cancer immune deficient patient due to a *Lactobacillus rhamnosus* probiotic infection and another case of a patient that had sepsis infection). Fish oil supplements, showed "to benefit cancer patients by maintaining their weight and muscle mass during chemotherapy treatment." In addition to the benefits mentioned above, mind-body CAM had some evidence for patients undergoing chemotherapy such as acupuncture, mild exercise, hypnosis, imagery/relaxation, massage, meditation, self-expression and music. The benefits of these modalities are mainly in treating chemotherapy induced vomiting, nausea and anxiety. Mild exercise was evident to decrease "fatigue" and increase "life satisfaction", yoga to "reduce stress and improve the quality of life", hypnosis was also evident "to

modulate immune function" during the course of treatment while meditation "alters the immune system" by its power in decreasing stress. Self-expression helps the patient in "expressing her emotions" in a positive way and thus "decreases dark feelings" associated with her breast cancer and disease state (Smith, Clavarino, Long and Steadman 2014).

A recent prospective-cohort study done in Korea over 481 terminal state cancer patients showed that CAM users did not have additional benefits as compared with non-users. They didn't have better survival than the non-users moreover they reported clinically significant worse changes in certain health-related quality of life subscales. For example cam-users had worse survival, cognitive functioning, more fatigue compared to nonusers (Yun *et al*. 2013).

A common belief among patients with cancer is that treatment with shark cartilage positively impacts overall survival of advanced cancer that are already on conventional cancer treatments. A two-arm, randomized, placebo-controlled, double blinded, clinical trial was done to evaluate this hypothesis. The results conducted by this study showed no perceived benefits for patients receiving conventional treatment with the shark cartilage product compared to the conventional treatment with placebo. In addition to that finding the study also showed that there was no improvement in the quality of life for patients receiving the shark cartilage compared to the placebo group (Loprinzi *et al*. 2005).

A review conducted on the safety of herbal medical products on women with breast cancer. Black cohosh, which is a species of a flowering plant, an herb commonly used and phytoestrogen, which are plant derived xenoestrogens not generated within the endocrine system rather consumed by phytoestrogenic plants, received great attention with regard to their ability to relief breast cancer patients from hot flushes. This review

concluded that "black cohosh" may have a positive benefit for flushes over placebo trials. Opposing effects have been linked to dietary phytoestrogens however the latter having a positive effect on tumor recurrence (Roberts 2010).

a. Complications Associated With CAM Use

The regulatory status of CAM use poses a global challenge since there are no guidelines for CAM practice, ignorance on CAM modalities, absence of licensing among CAM practitioners, also in availability of data on the usage of CAM and finally the gap in communication and organization between CAM providers and the health care system (Fink 2002; Meeker 2000) Moreover the Middle East and North Africa region (MENA) hosts one of the fastest growing markets of CAM products in the world little is known about CAM use in the region (Gruenwald and Herzberg 2002). The situation is similar to Lebanon where there is absence of regulations in this market despite its rapid and steady growth among the Lebanese population (Alameddine, Naja, Abdel-Salam, Maalouf and Matta 2011).

Alternative therapies are promoted to replace the "orthodox" conventional treatment however this is highly controversial and its overall effectiveness is possibility of remission and cure in cancer patients. In addition to this, interventions sold as alternatives to any cancer treatment ranging from surgery to chemotherapy or radiation tend to be biologically active, possibly harmful and in many cases costly (Cassileth and Deng 2004).

There are several motivations behind the use of CAM among cancer patients, and regardless of their motivation, the use of CAM is rarely evident based. Although there might be some kind of benefit, the potential harm associated to some CAM therapies is profound and will be discussed in detail (Smith *et al*. 2014).

The safety of many CAM therapies is in question ranging from transient side effects to more harmful and serious interactions. Other than the side effects, CAM use can lead to drug interactions that can decrease the efficiency of the conventional treatment for cancer in addition to adding economic costly burden on participants with a cost range from few cents to thousands of euros spent per modality (Hubner and Hanf 2013).

The European survey that included 14 countries concluded that 4.4% of cancer patients reported side-effects from CAM therapies used. Most of which were temporary and majorly due to certain herbs or minerals taken. The side-effects reported in this survey were mild and didn't persist for a long time such as stomach aches with" thyme and nettle tea, vitamin C and with aloe", gastric upset and nausea "with nettle tea", itching "with nettle leaves, selenium supplement and with mistletoe", headaches/migraine "with unspecified herb", diarrhea "with unspecified herb" and poor renal status/accumulation of body acid "with vitamin C" (Molassiotis *et al*. 2005).

A review done on published articles on the herbal therapies used among cancer patients included 43 articles describing 71 individual case reports. Of those studies 21 case reports concluded toxic effects of herbs used by cancer patients. Of those 21 cases, 6 were associated with traditional Chinese medicine (TCM), another 6 with herbal mixes, 2 with the use of PC-SPES (drug sold marketed to treat cancer especially prostate cancer), 2 with mistletoe and the rest with different unidentified herbs. Serious side effects were witnessed by the patients taking PC-SPES such as pulmonary embolism and disseminated intravascular coagulation. Moreover the usage of mistletoe was associated with delayed type hypersensitivity and hyperosinophilia in the treatment of breast cancer. Also certain TCM that contain aristolochic acid was found to cause renal failure and nephropathy. Other mixtures of herbs such as "chaparral, flaxeed,

alfalfa, red clover, licorice, ginkgo, ginseng and huang qi" also had negative effect on breast cancer patients such as delayed hypersensitivity reactions, hypokalemia, metabolic alkalosis, hyponatremia and some drug interactions. (Olaku and White 2011)

Moreover, antioxidants used without the actual micronutrient deficiency among cancer patients undergoing chemotherapy or radiation therapy might reduce the efficacy of the conventional therapy on the tumor cells (Bairati *et al*. 2006; Bairati *et al.* 2005; Meyer *et al*. 2007). A review done on several RCTs that studied the effect of antioxidant use among patients during chemotherapy and radiation therapy had a similar finding and concluded that the use of antioxidant supplements during cancer therapy should be discouraged since it likely protects the tumor and decreases survival of the patients (Lawenda *et al*. 2008).

Common adverse side effects that accompany certain CAM modalities used by cancer patients include allergic reactions (Echinacea used for strengthening the immune system), photosensitivity (St. John's wort used for depression), dermatologic skin reactions and gastrointestinal complications (milk thristle commonly used as a "detoxifier", and hepatotoxicity (by black cohosh that are intended to treat menopausal symptoms). In addition to those multiple side effects caused by some CAM therapies used among cancer patients many may render conventional cancer therapy. They render the cancer treatment by either becoming more toxic or becoming a sub-therapeutic, either one results in compromising cancer treatment (De Smet 2004; Tascilar, de Jong, Verweij and Mathijssen 2006).

b. Disclosure of CAM Use

Communication between patients and their health care providers is essential especially when it concerns cancer patients, specifically breast cancer patients. The use

of CAM was unrecognized however now CAM use among breast cancer patients is very common and the interest in the use of CAM is growing. Therefore the disclosure to the treating physician over CAM use is highly important especially when the patient is ongoing cancer treatment in order to maintain patients' safety, reduce the risk factors that accompany some CAM modalities commonly used among cancer patients, and the overall well-being of those patients (Alferi *et al*. 2001; Hubner and Hanf 2013).

A 5-year cohort study was done that consisted for a 4 interview cycle that aimed in understanding the reasons for nondisclosure of CAM use to the physician and healthcare provider. The results showed that patients feared the physicians' lack of interest, negative response, unwillingness or inability to positively contribute helpful information regarding that matter, their opinion that CAM therapies used were irrelevant to the conventional treatment course and their views on the appropriate coordination of disparate healing strategies (Adler and Fosket 1999).

From a German study mentioned earlier, reasons for not disclosing CAM use among breast cancer patients using CAM majorly was "simply not having been asked about CAM" (25%) followed by other reasons such as "the inpatient setting is not the right setting to talk about CAM" (11%)," I don't believe the inpatient specialist approves CAM" (8%). Also, when asked about supporting and discouraging reactions to CAM use where the patients would fill in freely the space provided ; the most noticeable negative interactions documented were associated with inpatient oncology specialists (41%) whereas GPs, families and friends and even gynecologists were generally supportive (Tautz *et al.* 2012). Another study done in Germany found out that 69% of CAM users among breast cancer patients enrolled in that study disclosed about their usage of CAM therapy to their oncologist. However 31% of those patients didn't disclose this matter to their treating doctor. Moreover in that study several questions

revolved around the communication between the physician and patient towards CAM use where, only 16% of the patients believed that their oncologist was well-informed about the different CAM therapies. Almost half of the participants 46%, relied on naturopaths and non-medical specialists regarding CAM use (Huebner *et al*. 2014).

Another study done that aimed in describing the communication patters of breast cancer patients with their treating oncologist on CAM use. They found out that 24% of the patients discussed CAM use at least at 1 instance with their oncologist. Other findings were that the majority of those discussions (73%), were started by the patient. Out of those discussions 38% of the patients reported encouraging comments, 23% were discouraging comments. In addition to that, around 20% of the discussions over the use CAM therapies were ignored by the physician (Juraskova, Hegedus, Butow, Smith and Schofield 2010).

A systematic review included 21 studies that investigated the communication between cancer patients that were using CAM therapies and their physician concluded that of these patients (20%-77%) did not disclose their CAM use with the majority for the nondisclosure rate between 40%-50%. This review showed the lack of communication between the physician and patient. The main reasons noted for not disclosing CAM use were doctors' ignorance, disapproval, lack of interest, incapable in providing information on CAM therapies and patients felt that their CAM use was of no importance to their conventional treatment. Additional reasons for not disclosing their CAM use did consultation time restraints and the patients want to have complete individualized control over their treatment (Davis, Oh, Butow, Mullan and Clarke 2012).

A semi-structured interview with 143 cancer patients was conducted where patients recorded their experience with CAM use showed that the majority of users tend

to not disclose CAM use. According to the patients' point of view the main barriers for disclosure on CAM use were the physicians' opposition towards CAM, his/her emphasis on scientific evidence and the patients' expectation of negative response from their treating doctor (Tasaki, Maskarinec, Shumay, Tatsumura and Kakai 2002).

A study conducted in 2008 in Anatolia, Turkey included 268 cancer patients. The results of that study were that 43% of the sample were using or had used CAM therapy and that out of those 43% only 23.1% of the sample discussed their use of CAM with their physician (Er, Mistik, Ozkan, Ozturk and Altinbas 2008).

In a study mentioned earlier on the use of CAM therapies among diabetic patients in Lebanon, only 7% of the CAM users disclosed CAM use to their treating physician while 93% hadn't consulted their doctor before using CAM therapy (Naja *et al.*, 2014).

From the Lebanese study of CAM use among pediatric Leukemia patients conducted, less than one third of CAM users reported their use of CAM therapies to their physician (Naja *et al*. 2011).

C. Summary

With the increasing incidence of CAM use around the globe including Lebanon, a country where CAM use is prevalent, common and culturally acceptable, up until now there is no data on the prevalence and determinants of CAM use among Lebanese breast cancer patients. Moreover since CAM is gaining popularity and growing among breast cancer patients and the restraints patients feel, makes the knowledge of CAM therapies essential for physicians and healthcare providers. Oncologists should be open to the subject and should be keen in initiating discussions and allowing for communication on the use of CAM therapies among their patients pro-

actively. This way breast cancer patients become protected from slipping away into an alternative world where advice is given from unreliable sources such as other patients, family, friends or information found over the internet all of which are very far from the "orthodox" conventional treatment for their breast cancer. In addition to that, literature still is insufficient with evident data that suggest the efficacy of CAM therapies used among those patients (Nahleh and Tabbara 2003; Tautz *et al*. 2012). This study will help in setting the foundation for future research on the efficacy and safety of CAM treatments on the prognosis of breast cancer. It will enhance the understanding of physicians on the prevalence of CAM use among breast cancer patients, as well as to encourage the implementation of a patient-centered care. Moreover adding to the knowledge of researchers and policy makers on the potential risks and benefits that are correlated with CAM use.

D. Objective and Aim of This Study

This present study aims at examining the prevalence, determinants, modes and types of CAM use among breast cancer patients in Beirut, Lebanon. The result of this study will help set foundation for future studies concerning the effectiveness of CAM treatments in the improvement of breast cancer prognosis and to enhance the understanding of physicians on the frequency of CAM use among breast cancer patients, allowing for the possible improvement as well as the implementation of a patient-centered care. More specifically the aims of the study are as follow:

- Assess the prevalence, frequency and mode of use of CAM among breast cancer patients.
- Examine the determinants of CAM use among breast cancer patients (demographic, socio-cultural, economic and medical).

- Investigate the type of CAM treatments used among breast cancer patients.
- Assess patients' perceived benefits or adverse effects attributed to CAM use.
- Assess the disclosure of CAM use to medical care providers.

CHAPTER II

METHODOLOGY AND MATERIALS

A. Study Design

This is a cross-sectional study, conducted between October 2013 and August 2014, assessing the prevalence, types, modes and determinants of CAM use among Lebanese breast cancer patients.

B. Ethical Approval

The Institutional Review Board (IRB) of the Social and Behavioral Sciences at the American University of Beirut (AUB), as well the ethics committee review at Makassed General Hospital (MGH) approved the protocol of this study (IRB Letter of Approval and IRB Continuing Review Form – Appendices I and II)

All research assistants/interviewers that were involved in this study have successfully completed the Collaborative Institutional Training Initiative (CITI) course as per the requirement from the IRB. The trained research assistants obtained a written consent from patients agreeing to participate in this study prior the completion of the questionnaire. The interviewers emphasized that the patients' answers are confidential and will not be exposed to their health care providers. Moreover, the interviewers and collaborators to this study had no access over the medical records of any of the patients.

C. Study Population

For patients to be able to participate in this study they had to be females, older than 18 years of age, of a Lebanese nationality, conversant in either Arabic or English

language and diagnosed for breast cancer for at least two months. The two months duration allowed time for participants to explore the different CAM therapies available. Moreover, patients that were not able to give consent prior to participation were excluded from the study. The subjects were recruited from two major health care facilities in Beirut a private not-for-profit philanthropic and a private academic medical center. Both are accredited by the Lebanese Ministry of Health (MoH) and attract the largest population of the patient population in Lebanon. The philanthropic private hospital generally serves patients coming from a lower socio-economic status as compared to the private academic medical center. The pool of the study participants will include patients being followed at Basile Cancer Institute at AUBMC or MGH at the outpatient clinics in both health care facilities as well as breast cancer patients presenting for chemotherapy administration. The sample population consisted of 180 females visiting either AUBMC or MGH.

D. Protocol

Recruitment of breast cancer patients took place at the waiting room in the clinics. The nurse in charge introduced the study to the patients. Then, trained research assistants approached interested patients and further explained the study and obtained a written consent for the interview and data collection for patients that agreed to participate. After agreeing to participate in the study, the research assistants invited the participants to a private office where they signed the consent and discussed the study in total privacy. After signing the written consent, the research assistants administered the questionnaire to the patients. Face-to face interviews were carried on where the questionnaires were filled with the help of the trained research assistants/interviewers involved in this study that have completed the CITII course. The research assistants

maintained standardized techniques in order to decrease interviewer bias. Both the questionnaire and the written consent form were available in both languages Arabic and English, depending on the patients' preference. To ensure a representative cross-sectional sample of the patients from the two participating medical centers, interviews were carried on different days of the week and at varying times.

E. Sample Size Calculation

The calculations for the sample size were based on 30%, 40% and 50% estimates of prevalence of CAM use for various confidence intervals. They are presented in the following table.

Table 1. Sample size required for selected widths of 95% confidence intervals with 30, 40 and 50% prevalence of CAM use among breast cancer patients

	Prevalence estimates of CAM use								
	30%			**40%**			**50%**		
	±5%	**±7%**	**±10%**	**±5%**	**±7%**	**±10%**	**±5%**	**±7%**	**±10%**
Number of subjects needed	318	164	81	363	187	60	377	195	96

Thus the sample of 180 subjects with breast cancer will be required to allow a width of 95% confidence internal not greater than ± 7% at a prevalence of 40%.

F. Data Collection

1. Questionnaire

The CAM questionnaire (Questionnaire, Arabic and English version, Appendix IV) was developed and the content validity of the multi-component questionnaire was

confirmed by a panel of experts that included an oncologist, a nutrition epidemiologist and a health policy expert. The questionnaire was primarily written in English then translated to the Arabic language by a professional translator. The translated Arabic version of the questionnaire was back translated by a professional translator to make sure the parallel-form reliability of the questionnaire. Moreover, the original and back translated versions were reviewed for consistency in meaning by two bilingual experts.

The questionnaire was comprised of three sections; the first section, socio-demographic and lifestyle characteristics of the participants' age, marital status, educational level, employment status and health insurance. The second section, included questions specific to their breast cancer diagnosis such as the age of diagnosis, history of cancer in their family and perception of their health status. The third and final section of the questionnaire included questions assessing the type of CAM treatments used, their mode of use (as complementary or alternative to conventional medical treatment), frequency of use, cost, perceived benefits, purpose of use, and disclosure of use to the physician.

A pilot study was conducted with 15 selected breast cancer patients prior initiation of the study to ensure that the target population understood the different sections of the questionnaire and that the answers yielded the required data. The findings of the pilot study were included in the analysis of the present study.

Some socio-demographic characteristics variables were further grouped before including them in the analysis, mainly because of the small numbers in each category. Such as education level was categorized as "high school or less", this category included illiterate, primary and secondary school while the other category was "university degree" and included patients with diploma, bachelor, masters or doctoral degree. Whereas the employment status was categorized as "employed" and "unemployed";

those employed are anyone with a current job on the other hand the unemployed category were those who are unemployed, retired and housewives. The insurance category was divided into 2 groups the "private" being the private and self-paying and the" public" that group included the MoH and the social such as NSSF, COOP, army and the public security. Income was also categorized into 3 groups; participants having less than $500 per month as the primary group followed by participants having between $500-$1000 and the last group were participants having an income of more than $1000 per month. Crowding index was calculated as the number of persons living in the same household per the number of rooms available in that household.

2. Complementary and Alternative Medicine Intake Assessment

CAM was defined as per the definition mentioned earlier by the NCCAM (NCCAM 1992). In this study, CAM use was defined as using CAM at least once since the diagnosis with breast cancer. The different types of CAM used identified in our study findings were classified into various categories. Those categories are vitamins and mineral supplements, special foods, herbal tea, dietary supplements, spiritual healing and other modalities.

G. Choice of Medical Institutions

The two medical institutions selected for conducting this study are the Basile Cancer Institute (AUBMC) and in Makassed General Hospital (MGH). Before conducting the study, both hospitals agreed in participating in this research project.

1. Basile Cancer Institute at the American University of Beirut Medical Center (AUBMC)

Basile Cancer institute at AUBMC is an adult cancer facility that provides a comprehensive cancer treatment for oncology patients and undergoes continuous research. It includes a multidisciplinary specialized group that is able to diagnose and manage the treatment of patients with cancer.

AUBMC is one of the most outstanding medical institutions in the Middle East and in Lebanon. It is located in Beirut, the Capital of Lebanon. AUBMC is a non-profitable private health care center founded 145 years ago. Today AUBMC offers 420 beds services in various medical specialties such as surgery, pediatrics, obstetrics and gynecology, psychiatry and a cancer unit AUMBC is the only medical institution in the region that have earned a four star international accreditations of the Joint Commission International (JCI), Magnet recognition for nursing excellence, College of American Pathologists (CAP) for pathology/laboratory services, and the Accreditation Council for Graduate Medical Education – International (ACGME-I) for graduate medical education. AUBMC, influences the medical sector and have guided the medical field in the region in providing high standards in patient-centered health care, education and continuous research.

2. Makassed General Hospital (MGH)

MGH is an academic hospital that was founded in 1930. It serves 200 beds for patients seeking different medical specialties. Includes around 125 specialized doctors, 322 nurses and around 350 administrative employees. MGH provides medical health services in different specialties such as internal medicine, pediatric, surgery, obstetrics and gynecology out-patient clinics and many more. MGH established the first Bone

Marrow Transplant Center in Lebanon. It is also located in the Capital Beirut.

H. Statistical Analysis

First the data was checked for completeness, and responses were coded and entered into the Statistical Package for the Social Sciences (SPSS) software version 21.0 for windows. Descriptive statistics were expressed as frequencies and percentages as well as means and standard deviations for describing categorical and continuous variables, respectively. CAM use, was the main outcome in this study, was dichotomous and defined as either using CAM at least once since diagnosis with breast cancer or not. Independent t-test for the continuous variables (age) and chi-squared test for the different categorical variables were used to compare variables between users and non-users of CAM. Similar analyses were performed to compare variables between CAM users that disclosed their CAM use to their physician as compared to CAM-users that did not disclose their CAM use to their physician. Statistical significance was detected by a p-value less than 0.05.

Univariate and multivariate logistic regression analyses were applied to determine which factors are associated with the use of CAM and similar analyses that determined the factors associated with disclosure of CAM use to the physician while allowing for the control of any confounding variables. Univariate and multivariate logistic regression analyses were applied to determine which factors are associated with the use of CAM and which factors are associated with disclosure of the use of CAM to the physician. The dependent variable in the multi logistic regression analysis was the use/no use of CAM and the independent variables included the age and the different variables that showed statistical significance in the chi-square analysis of the bivariate analysis. Also, similarly another multi logistic regression analysis was done on

disclosure on the use of CAM to their physician or no disclosure and the independent variables included the age and the different variables that showed statistical significance in the chi-square analysis. The effect of each variable on the model was assessed and the variable was kept if it significantly contributed to a better fit of the model. Odds ratios and their respective 95% confidence intervals were calculated.

I. List of Variables

A descriptions of the variables used in this study are presented in Table 2. These variables are derived from the questionnaire used in this study.

Table 2. List of variables and their description

Category	Variables	Description	Coding
Demographic Characteristics	Age	Indicated by number of years	
	Place of residence		Open-ended
	Marital Status	Indicated by the marital status	Single(not married, separated, widowed, divorced), married / living with a partner
	Monthly household income	A measure of socio-economic status ; indicated by the amount of money earned per month	< 500$/month, 500-1000$/month, 1000-2000$/month, >2000$/month
	Level of education	Indicated by the highest level of education reached by the patient	Illiterate, School: primary, Secondary; baccalaureate, Diploma; University; Bachelor, Masters; Doctoral
	Employment status	Indicated by whether the patient has a job	Employed, Retired, Housewife, Unemployed, Other
	Current occupation		Open-ended
	Number of persons in the house	Indicated by the number of persons residing in the house excluding newborns	
	Number of rooms in the household	Indicated by the number of rooms in a household excluding the toilet, kitchen, balcony and garage	

"Table 2 – *Continued*"

Category	Variables	Description	Coding
	Crowding Index	It is the number of usual residents in a household divided by the number of rooms in the household	<1 1-2 >2
	Health insurance	Indicated by how the patient covers his/her medical expenses	Public, Social, Private, Self-paying
Breast Cancer	Duration of diagnosis	Indicated by the duration in years	
	Current stage of Cancer	Indicated by the stage	Metastatic, Locally advanced, early stage
	Site of metastasis		Open-ended
	Family history of Breast Cancer		Yes, No. If yes, relation to patient
	Family history of other Cancers		Yes, No. If yes, Please specify
	Presence of any medical condition		Hypertension, CVD, obstructive pulmonary disease, others
	Adherence to recommendations		Yes, No
	Main barriers to adherence to recommendations		Unaffordable medication, intolerance of drug side-effects, other
	Received Dietary advice		Yes, No
	Source of Dietary advice		Doctor, nurse, Dietitian (referral, personal decision)
	Symptom		Drop down list, other
	Most distressing symptom		Open-ended
	Current state of health		Very poor, poor, Fair, Good, Excellent
CAM use	CAM use since diagnosis		Yes, No
	CAM use over the last 12 months		Yes, No
	Mode of use		Alternative, Complementary
	Purpose of use	Indicated by the reasons for use of CAM	Treatment, relief of symptoms and prevention of suffering
	Reasons for not using CAM	Indicated by the type of CAM products used by patients	Drop down list, other
	Doctor opinion		Yes, No
	Reaction of Doctor		Encouraging,

"Table 2 – *Continued*"

Category	Variables	Description	Coding
			Discouraging, Neutral
	Type of CAM		Drop down list, other
	Choice of CAM		Drop down list
	Frequency of use		One time, regular, once per month, other
	Provider of treatments		Massage therapist, acupuncturist, a practitioner of traditional medicine, a naturopath, a homeopath
	Cost of CAM	Indicated by amount in $ per month	Drop down list
	Reasons for CAM use		Drop down list
	Expectation when using CAM	Indicated by the patients' expectation as a result of CAM use	Drop down list, other
	Satisfaction with outcome		Not at all, somehow, very satisfied, can't tell
	Any side effect		Yes, No, undecided
	Use CAM again		Yes, No, undecided
	Recommend CAM use		Yes, No, undecided

CHAPTER III

RESULTS

A. Socio-Demographic and Disease-Related Characteristics of the Study Population

Out of 190 breast cancer patients invited to participate in this study, 180 completed the survey. The response rate was 94.7%; the main reason for refusing to participate was the lack of time and interest in the objectives of the study.

Table 3 displays the socio-demographic and disease-related characteristics of the study population. The mean age of the patients was 53.78 ± 9.93 years. Their distribution between the private academic medical center and the philanthropic private hospital was 64.4% vs 35.6%, respectively. Around 80% of the participants were married and 68.9% had a university degree. At the time of the questionnaire, only 28.9% of the participants were employed and almost 52% had a crowding index of <1. Among the participants, only one in four had a private health insure (24.4%). Only 20.1% of the participants monthly income was <500$, while 38.5% had both a monthly income between 500 -700$ and an income of more than 1000$.

The majority of the participants (39.4 %) had been diagnosed with breast cancer in less than a year from conducting this study and 58% of the subjects didn't have any family history of breast cancer. Fifty five percent of the patients had an early stage of breast cancer and a high proportion indicated adherence to the doctor's recommendations (93.3%). Only 31 patients (17.2%) indicated that their health status was either poor or very poor.

Table 3. Socio-Demographic and Disease-Related Characteristics of the Study Population (n=180)

Characteristics	**n (%)***
Age (years)	53.78±9.93
Recruitment site	
Private medical center	116 (64.4)
Philanthropic private hospital	64 (35.6)
Marital status	
Single	35(19.4)
Married	145(80.6)
Educational level	
High school or less	56(31.1)
University degree	124(68.9)
Employment status	
Unemployed	128(71.1)
Employed	52(28.9)
Crowding index	
<1	93(51.7)
≥1	87(48.3)
Type of health insurance	
Private	44(24.4)
Public	136(75.6)
Monthly income	
<500$	36(20.1)
500-1000$	74(38.5)
>1000$	69(38.5)
Duration of breast cancer	
< 1 year	71(39.4)
1-5 years	66(36.7)
>5 years	43(23.9)
Family history of breast cancer	
No	105(58.3)
Yes	75(41.7)
State of breast cancer	
Early stage	99(55)
Locally advanced	44(24.4)
Metastatic	37(20.6)
Adhere to doctor's recommendations	
No	12(6.7)
Yes	168(93.3)
Current state of health	
Poor/very poor	31(17.2)
Fair	65(46.7)
Good/ very good	84(46.7)

*Values in this table represent n (%), except for age where mean ± standard deviation (SD) is reported

B. The Association of Socio-Demographic and Disease-Related Characteristics with CAM Use in the Study Population (n=180)

The socio-demographic, disease-related characteristics with CAM use in the study population are shown in Table 4.

CAM users were significantly younger compared to non-users (50.78 vs. 55.64, $p<0.01$) and they were more likely to be married (89% vs. 74.8%, $p<0.05$). The vast majority of CAM-users were recruited from the private medical center as compared to non-users (87.7% vs. 48.6%, $P<0.01$). Moreover CAM-use was higher among patients with more advanced stage of the disease, metastatic as compared with non-use (27.4% vs. 15.9%, $P<0.05$).

Table 4. Association of Socio-Demographic and Disease-Related Characteristics with CAM Use In the Study Population (n=180)

Characteristics	**CAM users n=73**	**CAM non-users n=107**	**P-value**
Age (years)	50.78±10	55.64±9.32	**0.001**
Recruitment site			
Private medical center	64(87.7)	52(48.6)	**0.00**
Philanthropic private hospital	9(12.3)	55(51.4)	
Marital status			
Single	8(11)	27(25.2)	**0.018**
Married	65(89)	80(74.8)	
Educational level			
High school or less	50(68.5)	77(72.0)	0.616
University degree	23(31.5)	30(28.0)	
Employment status			
Unemployed	51(69.9)	77(72)	0.760
Employed	22(30.1)	30(28)	
Crowding index			
<1	34(46.6)	59(55.1)	0.259
≥1	39(53.4)	48(44.9)	
Type of health insurance			
Private	23(31.5)	27(25.2)	0.356
Public	50(68.5)	80(74.8)	

"Table 4 – *Continued*"

Characteristics	**CAM users n=73**	**CAM non-users n=107**	**P-value**
Monthly income			
<500$	9(12.3)	27(25.5)	0.098
500-1000$	33(45.2)	41(38.7)	
>1000$	31(42.5)	38(35.8)	
Duration of breast cancer			
< 1 year	32(43.8)	39(36.4)	0.577
1-5 years	24(32.9)	42(39.3)	
>5 years	17(23.3)	26(24.3)	
Family history of breast cancer			
No	43(58.9)	62(57.9)	0.898
Yes	30(41.1)	45(42.1)	
State of breast cancer			
Early stage	32(43.8)	67(62.6)	**0.038**
Locally advanced	21(28.8)	23(21.5)	
Metastatic	20(27.4)	17(15.9)	
Adhere to doctor's recommendations			
No	6(8.2)	6(5.6)	0.490
Yes	67(91.8)	101(94.4)	
Current state of health			
Poor/very poor	16(21.9)	15(14)	0.087
Fair	30(41.1)	35(32.7)	
Good/ very good	27(37.0)	57(53.3)	

No significant difference was found between CAM-use and non-use in different characteristics such as educational level, employment status, crowding index, type of health insurance, monthly income, duration of breast cancer, family history of breast cancer, adhere to doctors recommendations and state of health. Nonetheless, a higher percentage of patients with a university degree was observed among CAM-users as compared to non-users (31.5% vs. 28%), higher monthly income >1000$ (42.0% vs. 35.8%) and had a poor or very poor health status (21.9% vs. 14%).

C. Association of Socio-Demographic and Disease-Related Characteristics with CAM Use In the Study Population, As Derived From Logistic Regression

Table 5 shows the association of socio-demographic and disease-related characteristics with CAM use in the study population, (n=180). Bivariate logistic regression was used, significant differences associated with CAM use were age, recruitment site, marital status, monthly income and the state of breast cancer.

Table 5. Association of Socio-Demographic and Disease-Related Characteristics with CAM Use In the Study Population (N=180), As Derived From Logistic Regression

Characteristics	**OR (95% CI)**
Age (years)	**0.95(0.92-0.98)**
Recruitment site	
Private medical center	1
Philanthropic private hospital	**0.13(0.06-0.29)**
Marital status	
Single	1
Married	**2.74(1.17-6.44)**
Educational level	
High school or less	1
University degree	1.68(0.87-3.27)
Employment status	
Unemployed	1
Employed	0.90(0.47-1.74)
Crowding index	
<1	1
≥1	1.41(0.78-2.56)
Type of health insurance	
Private	1
Public	0.60(0.30-1.19)
Monthly income	
<500$	1
500-1000$	2.42(0.99-5.84)
>1000$	**2.45(1.00-5.97)**
Duration of breast cancer	
< 1 year	1
1-5 years	0.70(0.35-1.38)
>5 years	0.80(0.37-1.72)
Family history of breast cancer	
No	1
Yes	1.04(0.579-1.90)

"Table 5 – *Continued*"

Characteristics	OR (95% CI)
State of breast cancer	
Early stage	1
Locally advanced	1.91(0.93-3.95)
Metastatic	**2.46(1.14-5.33**
Adhere to doctor's recommendations	
No	1
Yes	1.51(0.47-4.87)
Current state of health	
Poor/very poor	1
Fair	0.80(0.34-1.89)
Good/ very good	0.44(0.19-1.03)

CAM use decreased with increasing age (OR: 0.95; CI: 0.92-0.98). Compared to subjects recruited from the academic medical center, those from the private philanthropic hospital had lower odds of using CAM (OR: 0.13; CI: 0.06-0.29). Married subjects were more likely to use CAM as compared to single subjects (OR: 2.74; CI: 1.17-6.44). The higher the income, the greater was the odd of using CAM, with subjects reporting an income greater than 1000$ having almost two and a half times the odds of using CAM as compared to those reporting an income less than 500$ (OR: 2.45; CI: 1.00-5.97).

Furthermore, the odds of CAM use increased to almost two and a half with more advanced stages of the disease to reach 2.46 (CI: 1.14-5.33) for patients with metastatic cancer as compared to early stage.

D. Multivariate Logistic Regression for the Correlates of CAM use in the study population

The results of the multivariate logistic regression model used to examine the correlates of CAM use in the study population are presented in Table 6.

The final model included the following variables: age, recruitment site, marital status, education level, health insurance, monthly income, family history of breast cancer and state of breast cancer. After adjustment, CAM use was found to decrease significantly with increasing age (OR: 0.96, CI: 0.92-0.99) and it was less among patients attending clinics at the private philanthropic hospital (OR: 0.12, CI: 0.04-0.32). Furthermore, compared to patients reporting an early stage of breast cancer, reporting an advanced stage of the disease was associated with a greater odd of CAM use (OR: 4.14, CI: 1.63-10.46).

Table 6. Multivariate logistic regression for correlates of CAM use in the study population (n=180)

Characteristic	**OR (95% CI)**
Age (years)	**0.96(0.92-0.99)**
Recruitment site	
Private medical center	**1**
Philanthropic private hospital	**0.12(0.04-0.32)**
Marital status	
Single	1
Married	1.76(0.63-4.87)
Education level	
High school or less	1
University degree	0.87(0.37-2.02)
Type of health insurance	
Public	1
Private	1.04(0.47-2.27)
Monthly income	
<500$	1
500-1000$	0.54(0.17-1.77)
>1000$	0.51(0.15-1.80)
Family history of breast cancer	
Yes	1
No	0.92(0.45-1.87)
State of breast cancer	
Early stage	**1**
Locally advanced	**4.14(1.63-10.46)**
Metastatic	1.88(0.79-4.49)

E. Prevalence, Modes and Characteristics of CAM Use in the Study Population

Table 7 describes the prevalence, modes and characteristics of CAM use among study participants.

Table 7. Prevalence, Modes and Characteristics of CAM Use in the Study Population (n=180)

Prevalence and types of CAM used among breast cancer women	n (%)
Used CAM in the previous year	
No	111(61.7)
Yes	69 (38.3)
Used CAM since diagnosis	
No	107(59.4)
Yes	73(40.6)
CAM used as complementary or alternative	
Complementary	73(100)
Alternative	0(0)
CAM related characteristics among CAM users (n= 73)	
CAM choice*	
Media	20 (27.4)
Family beliefs	20(27.4)
Personal choice	18(24.7)
Friends	8(11.0)
Health care practitioner	3(4.1)
Healthy food shop salesman	2(2.7)
Alternative medicine therapist	2(2.7)
Reasons of CAM use*	
Belief in advantages of CAM	67(91.2)
managing cancer complications and slowing its progression	56(76.7)
Reduce side effects of conventional therapy	25(34.2)
To feel more control over health	23(31.5)
Family tradition/culture	22(30.1)
Strengthen immunity	18(24.6)
Provides energy	11(15.1)
Provides hope/prayer	10(13.7)
Relief from sorcery and spell	5(6.6)
Disappointment from conventional therapy	3(4.1)
Curiosity	3(4.1)
CAM use for	
Treatment of breast cancer	59(80.8)
Relief of symptoms	4(5.5)
Both	10(13.7)

"Table 7 – *Continued*"

Prevalence and types of CAM used among breast cancer women	n (%)
How often is CAM used	
Twice or more per day	47(64.4)
Once per day	21(28.8)
Once per month	1(1.4)
Less than once per month	4(5.5)
Feeling after CAM use	
How do you assess the usefulness of CAM	
Not at all	5(6.8)
Some	43(58.9)
A lot, very satisfied	22(30.1)
You can't tell	3(4.1)
Side effects from CAM	
No	65(90.3)
Yes	7(9.7)
Would you use CAM again?	
No	4(5.6)
Yes	53(73.6)
Undecided	15(20.8)
Would you recommend CAM to other breast cancer patients?	
No	8(11.1)
Yes	38(52.8)
Undecided	26(36.1)
CAM related characteristics among non-users (n=107)	
Reasons for not using CAM*	
Lack of belief in the benefits of CAM	36 (33.6)
Afraid of side effect	30 (28.0)
The doctor didn't prescribe CAM	21 (19.6)
Never heard of CAM	11 (10.3)
Additional burden	9 (8.4)
Would you consider using CAM in the future	
No	91(85.8)
Yes	15(14.2)

*More than one answer was applicable

Out of the 180 patients surveyed, 73 reported using a form of CAM since diagnosis with the disease (prevalence of CAM use 40.6%, CI: 35%-48%). Also, among all CAM users (n=73), 100% reported using CAM as a complementary therapy to the conventional medical treatment; none as an alternative therapy.

When asked about the main influence of their CAM choice, the majority

reported either media (n=20; 27.4%) or family beliefs (n=20; 27.4%) and only 3 subjects (4.1%) indicated a heath care practitioner (n=3), a health food shop salesman (n=2) or an alternative medicine therapist (n=2).

The most commonly cited reason for using CAM was “belief in advantages of CAM” (91.2%), followed by “managing cancer complications and slowing its progression” (76.7%).

The reason for their use of CAM was "reduce side effects of conventional therapy" (34.2%), "to feel more control over health" (31.5%), "family tradition/culture" (30.1%), "strengthen immunity" (24.6%), "provides energy" (15.1%), "provides hope/prayer" (13.7%), "relief from sorcery and spell" (6.6%) and only 4.1 % reported their use for CAM was due to their "disappointment from conventional medicine" and for "curiosity".

When participants were asked to assess the usefulness of CAM, only 5 patients (6.8%) described the CAM they have used as “not useful at all”, and only 7 patients (9.7%) reported experiencing side effects due to CAM use. The majority of CAM users (73.6%) indicated that they will use it again. The main reasons for not using CAM among non-users were ‘lack of belief in the benefits of CAM’ (33.6%), ‘afraid of side effects’ (28.0%) and the fact that it is not prescribed by the treating physician (19.6%). The majority of non-users (85.8%) will not consider using a form of CAM in the future.

Figure 1, illustrates the frequencies of the various types of CAM used by the study population. The most commonly used CAM was ‘Special food’ (34.4%), followed by ‘Herbal teas’ (21.6%), ‘Diet supplements’ (16.8%), ‘Spiritual healing’ (12.8%), ‘Vitamins and minerals supplements’ (6.4%), and ‘Folk medicine’ (4.8%). Among the ‘Special foods’ reported were honey, black seed, camel milk, soy,

pomegranate, and ginger. 'Herbal tea' consisted mainly of 'Zhourat' (a special mix of locally produced herbal infusions) and green tea. Common 'Diet supplements' reported were prebiotic and graviola pills. 'Spiritual healing' was in the form of religion-specific practices such as prayers, lighting candles, pledging specific vows, consumption of foods deemed to be holly such as 'Zamzam water' (a holly water for Muslims, brought from Mecca), and fasting (abstinence from any food or drink from dawn to sunset). Multi-vitamins as well as iron pills were the main 'Vitamins and minerals supplements' reported. As for 'Folk medicine', it mainly consisted of bloodletting and cupping.

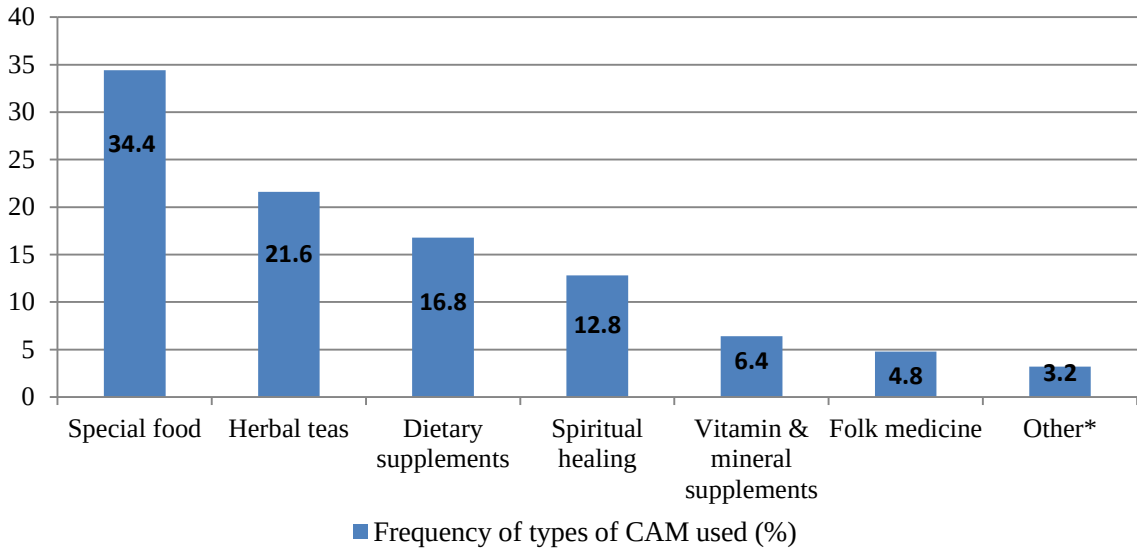

Fig. 1. Distribution of the various types of CAM used in the study population
*Other CAM reported were Aroma therapy (2); inhalation of Cannabis *'Hashishi'* (1), intake of Shark collagen (1).

F. Association of Socio-Demographic and Disease-Related Characteristics with Disclosure to the Physician among CAM Users

Table 8 shows the association of the socio-demographic and disease-related characteristics with disclosure to the physician among CAM users.

Table 8. Association of socio-demographic and disease-related characteristics with disclosure to the physician among CAM users (n=73)

Characteristics	**Disclosed n=20**	**Did not disclose n=53**	**P-value**
Age (years)	50.25±8.89	50.87 ±10.40	0.815
Recruitment site			
Private medical center	18(90)	46(86.8)	0.710
Philanthropic private hospital	2(10)	7(13.2)	
Marital status			
Single	1(5)	7(13.2)	0.317
Married	19(95)	46(86.8)	
Educational level			
High school or less	14(70)	36(67.9)	0.865
University degree	6(30)	17(32.1)	
Employment status			
Unemployed	16(80)	35(66.0)	0.246
Employed	4(20)	18(34)	
Crowding index			
<1	7(35)	27(50.9)	0.223
≥1	13(65)	26(49.1)	
Type of health insurance			
Private	15(75)	35(66.0)	0.462
Public	5(25.0)	18(34.0)	
Monthly income			
≤1000$	12(60)	30(56.6)	0.793
>1000$	8(40)	23(43.4)	
Duration of breast cancer			
< 1 year	4(20)	28(52.8)	**0.040**
1-5 years	9(45)	15(28.3)	
>5 years	7(35)	10(18.9)	
Family history of breast cancer			
No	11(55)	32(60.4)	0.677
Yes	9(45)	21(39.6)	
State of breast cancer			
Early stage	8(40)	24(45.3)	0.667
Locally advanced	5(25)	16(30.2)	
Metastatic	7(35)	13(24.5)	
Adhere to doctor's recommendations			
No	0	6(11.3)	0.116
Yes	20(100)	47(88.7)	
Current state of health			
Poor/very poor	5(25)	11(20.8)	0.210
Fair	5(25)	25(47.2)	
Good/ very good	10(50)	17(32.1)	

Patients who disclosed to their physician their use of CAM had higher longer durations of their disease (>5 years), as compared to patients that did not disclose their use of CAM (35 % vs. 18.9%, P<0.05).

No statistical significance was shown between patients that disclosed and patients that did not disclose their use of CAM in different socio-demographic and disease-related characteristics such as age, recruitment site, marital status, educational level, employment status, crowding index, type of health insurance, monthly income, family history of breast cancer, state of breast cancer, adherence to doctors recommendation and the current state of health.

G. Association of Socio-Demographic and Disease-Related Characteristics with Disclosure to the Physician among CAM Users as Derived from Logistic Regression

Table 9 shows the association of socio-demographic and disease-related characteristics with disclosure to the physician among CAM users (n=73). Bivariate logistic regression was used, significant difference associated with non-disclosure of CAM use was the duration of breast cancer.

Choosing not to disclose with the physician on the use of CAM decreased with the increase in duration of breast cancer, 1-5 years (OR: 0.23; CI: 0.06-0.90) and >5 years (OR: 0.23; CI: 0.06-0.90) as compared to < 1 year with breast cancer. So, it is like being more likely to disclose CAM use to the physician with longer duration of breast cancer.

The rate of CAM use disclosure to physicians and the reaction of the physician are described in Figure 2.The majority of CAM users (72.6%) did not disclose their use of CAM to the physician. Only 1 in four patients chose to report their CAM use to their physician. Upon disclosure, the reaction of the physician

was mainly discouraging (60%), with only 20%, reporting an encouraging reaction.

The remaining 20% of subjects reported a neutral reaction of the physician.

Table 9. Association of socio-demographic and disease-related characteristics with disclosure to the physician among CAM users (n=73), as derived from logistic regression

Characteristics	**OR (95% CI)**
Age (years)	1.00(0.95-1.06)
Recruitment site	
Private medical center	1
Philanthropic private hospital	1.34(0.25-7.07)
Marital status	
Single	1
Married	0.35(0.41-3.07)
Educational level	
High school or less	1
University degree	1.17(0.38-3.54)
Employment status	
Employed	1
Unemployed	0.50(0.15-1.72)
Crowding index	
<1	1
≥1	0.50(0.173-1.45)
Type of health insurance	
Public	1
Private	1.63(0.51-5.17)
Monthly income	
<1000$	1
>1000$	1.20(0.42-3.41)
Duration of breast cancer	
< 1 year	1
1-5 years	**0.238(0.06-0.90)**
>5 years	**0.22(0.05-0.92)**
Family history of breast cancer	
Yes	1
No	1.29(0.46-3.62)
State of breast cancer	
Early stage	1
Locally advanced	1.02(0.28-3.69)
Metastatic	0.59(0.18-2.00)
Current state of health	
Poor/very poor	1
Fair	2.27(0.54-9.48)
Good/ very good	0.82(0.22-3.03)

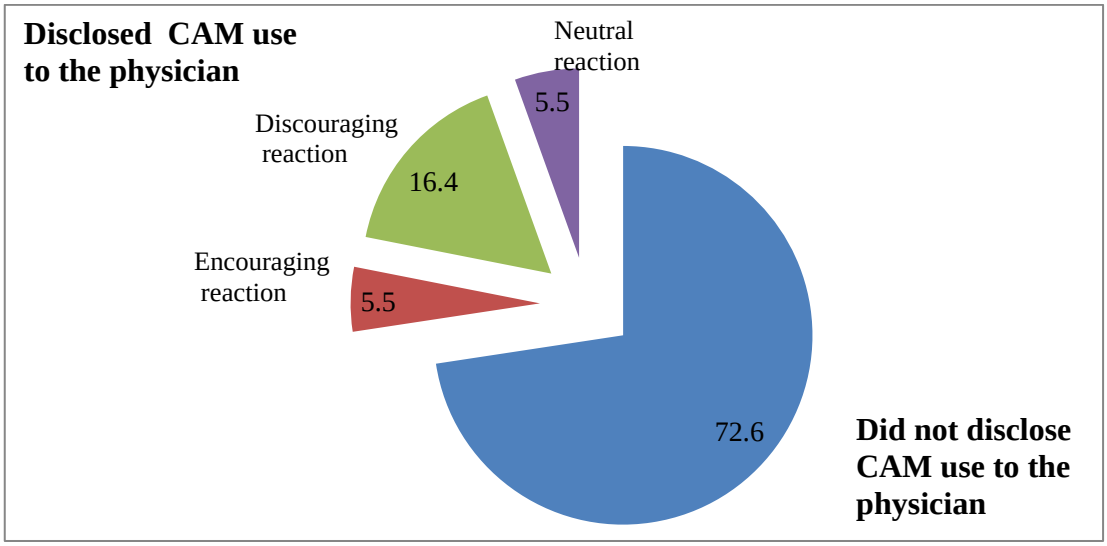

Fig. 2. Disclosure of CAM use to treating physician and the reaction of the physician, reported as percentage

H. Multivariate logistic regression for correlates for disclosure to the physician among CAM users

The results of the multivariate logistic regression model used to examine the correlates of disclosure to the physician among CAM users (n=73) are presented in Table 10.

The final model included the following variables: age, recruitment site, marital status, education level, health insurance, monthly income, family history of breast cancer, state of breast cancer and duration of breast cancer. After adjustment, choosing not to disclose CAM use to physician was found to decrease significantly with increasing duration of breast cancer (OR: 0.17, CI: 0.038-0.766) compared to patients with duration of breast cancer <1 year. Also here, it shows that patients having a longer duration of breast cancer tend to disclose their use of CAM more than patients with a shorter duration < 1 years of breast cancer.

Table 10. Multivariate logistic regression for correlates for disclosure to physician among CAM users (n=73)

Characteristic	**OR (95% CI)**
Age (years)	0.99(0.93-1.06)
Recruitment site	
Private medical center	1
Philanthropic private hospital	1.28(0.19-8.77)
Marital status	
Single	1
Married	0.23(0.02-2.66)
Education level	
High school or less	1
University degree	1.17(0.29-4.76)
Type of health insurance	
Public	1
Private	1.49(0.37-5.96)
Monthly income	
≤1000$	1
>1000$	1.12(0.29-4.38)
Family history of breast cancer	
Yes	1
No	1.58(0.48-5.26)
State of breast cancer	
Early stage	1
Locally advanced	0.86(0.18-4.21)
Metastatic	1.14(0.27-4.69)
Duration of breast cancer	
<1 year	**1**
1-5 years	**0.17(0.038-0.766)**
>5 years	0.22(0.05-1.03)

CHAPTER IV

DISCUSSION

A. Major Findings of This Study Highlighting the Prevalence of CAM Use Among Breast Cancer Patients

In this cross-sectional study, 180 breast cancer patients were surveyed about their use and perception towards CAM therapies. Our results showed that the prevalence on CAM use among breast cancer patients in Beirut, Lebanon is 40.6%. This estimate is almost equal to the findings of a nationwide cohort of Danish women with breast cancer, where 40.1% of those patients reported the use of CAM (Pedersen, Christensen, Jensen and Zachariae 2009). Moreover our estimate is very similar to a study done on 11 European countries where they found that 44.7% of breast cancer patient used CAM (Molassiotis *et al*. 2006). The prevalent use of CAM in this population and other study populations underlines the eagerness of breast cancer patients to explore different treatment modalities aiming to positively influence their attempt in fighting their disease. It is important to note a few studies that explored CAM use in breast cancer patients found higher estimates as compared to our study such as China (97%)(Chen *et al*. 2008), United States (86.1%)(Greenlee et al., 2009), Australia (80.1%)(Kremser *et al*., 2008), Malasia (70.7%) (Chui, Abdullah, Wong and Taib 2014) and Canada (66.7%) (Boon *et al*. 2000). The noted differences observed by geographic region could be due to differences in socio-cultural perception of CAM use, and may be due to disparities in the access and availability to conventional treatments. Moreover, different studies have different designs and definitions of CAM and this might have also contributed to making prevalence estimates of CAM use among breast cancer patients in these countries difficult to find (Chang, Wallis and Tiralongo 2007).

B. Correlates and Determinants of CAM Use among Breast Cancer Patients

Almost the majority of studies done on cancer patients and the general public internationally suggested that those that seek CAM therapies tend to be younger, more educated, are of higher socioeconomic status than those who don't seek CAM (Cassileth and Deng 2004). Similar findings were found in our study with regard to the correlates found to CAM use among breast cancer patients. Where CAM use was correlate to younger, more educated, as well as those with metastatic disease compared to patients that did not use CAM therapies. Similar findings were also found in a Canadian study on breast cancer patients were CAM users were younger, more educated and have higher household incomes. Furthermore a survey done in Malaysia, resulted that CAM users were more likely to have a tertiary education vs. primary/lower, have a greater household income and experience a more advanced state of cancer as compared to non-users (Chui *et al*. 2014). Likewise, a review on the socio-demographic factors correlated to CAM use among breast cancer patients found out that out of 29 studies, 22 reported that CAM users were the younger and higher educated as compared to older and women with lower education levels (Wanchai, Armer and Stewart 2010). Breast cancer patients with higher educational background tend to explore CAM therapies because they may be more health conscious, aware and exploit the different mainstream medical services than people that do not use CAM therapies. They also, are more likely to search for other therapies to deal with the disease and treatment side effects (Er, Mistik, Ozkan, Ozturk and Altinbas 2008). Moreover younger patients tend to be more distressed and anxious about their diagnosis and are thus keener to seek complementary therapies along with their conventional treatment. Also, patients with advanced stages of their cancer may have experienced higher stress and lower immune system thus may have influenced their choice in resorting to CAM to decrease their stressful situation and to

strengthen their immune system in order to fight their disease (Hlubocky, Ratain, Wen and Daugherty 2007). In addition to that, patients with metastatic diseases tend to have more symptoms and are dealing with an incurable disease where the efficiency of their standard therapies is at most palliative; therefore these patients tend to look for more therapies beyond their conventional treatment to fight their disease and to treat the varying side-effects.

C. Characteristics and Types of CAM Use among Breast Cancer Patients

In addition to the prevalence and determinants, the characteristics and types of CAM use were investigated in this study population. The findings showed that the majority of patients using CAM chose to do so based on input from the media and family belief (27.4%) each , personal choice (24.7%) and friends (11%). While very little patients chose their CAM based on health care specialists, healthy food shop salesperson or alternative medicine therapist. Majorly relying on the media, family and friends is a similar finding to several studies done in Lebanon on diabetic patients, infertility patients and pediatric leukemia patients were similar to our study findings were found in these studies (Ghazeeri, Awwad, Alameddine, Younes and Naja 2012; Naja *et al*. 2011; Naja *et al*. 2014; Naja, Alameddine, Abboud, Bustami and Al Halaby, 2011). Moreover, similar findings were in a study done in Ghana where the major influence on CAM use were friends (33.8%), the mass media (24.6%) and family (17%) (Yarney *et al*. 2013). Similar findings were also found in 11 European countries where also the source of information and influence on CAM use was majorly attributed to friends (64%), media (30.4%) and family (24.4%)(Molassiotis *et al*. 2006).

This finding is important especially with regard to the health policy makers as well as the medical community. Since the media plays an influential role in the patients'

choice in using CAM, the different modality, therefore policies should be directed towards filtering the messages propagated to patients and only allowing those of evidence based therapies and legitimate health claims.

D. Common Types of CAM Use by Breast Cancer Patients

In this study the most frequent CAM among breast cancer patients was biological based therapies that included special foods, herbal teas, dietary supplements as well as vitamin and minerals were the most commonly used CAM therapies in this study population. This finding is similar with earlier studies done (Can, Demir and Aydiner 2012; Wanchai *et al*. 2010).

Although the common types of CAM can differ from a country to another, the distribution of CAM modalities among breast cancer patients seem to revolve around a common spectrum of therapies and the most frequent used CAM have been identified as diet supplements, vitamin and minerals, special foods/diets /shakes (Alferi, Antoni, Ironson, Kilbourn and Carver 2001; Boon *et al*. 2000; Kremser *et al*. 2008). The high prevalence of the use of biological based therapies in this study can be explained by the fact that Lebanese and Arab herbalists have transmitted ancestral knowledge of a region earlier referred to as Bilad al Sham – the Levant – that was endowed with a high floral diversity which constituted a basis for health care in the region with very few species imported from outside it. These herbalists, managed to maintain relics of the traditions alive into the 21rst Century and they still include in their repertoire of medical use hundreds of plant species although only a small number of these plants have been investigated for their medicinal properties using contemporary evidence based medicine (unpublished article by Dr. Alameddine). Moreover, the prevalent use of these therapies could be due to the belief of cancer patients that such therapies are natural and nontoxic,

although such a belief is not based on scientific data (McLay, Stewart, George, Rore and Heys 2012). Furthermore, herbal remedies that are incorporated to traditional medicine can be toxic and are becoming very common and popular in the Middle East, although some of these therapies present minimal health hazards it remains important to note that some of these therapies interfere with the conventional treatments that these patients are receiving (Saad, Azaizeh, Abu-Hijleh and Said 2006). For example, some of the estrogen-rich therapies such as soy, used in this study, may not be recommended, especially for estrogen-positive breast cancer patients (McLay *et al*. 2012). Moreover the Turkish study done on breast cancer women undergoing chemotherapy highlighted the problematic dangers associated with the use of certain supplements especially antioxidants or complex botanical agents while undergoing conventional cancer treatment sue to drug-supplement interaction and side effects. Many of these were found to be used in this study such as anti-oxidant rich foods such as the black seed, pomegranate, garlic and ginger supplements all may have anticoagulant effects and may interact with adjuvant endocrine therapies. Moreover, many patients involved in this study reported the extensive use of green tea in treating their cancer, some evidence was shown from studies that green tea may have a beneficial effect in preventing the recurrence in early stage breast cancer yet patients cannot draw certain assumptions and conclusions based on a small number of studies conducted, the unavailability of clinical trial evidence, inconsistent dose-response relation and the highly possible interactions associated with their use of this herbal remedy and the conventional medical treatment (Can *et al*. 2012) . Given the potentially significant influence the biological therapies may have on the outcome of conventional treatment for breast cancer patients, it becomes very important to monitor patients' use of the different CAM therapies during treatment. In addition to the biological therapies used reported in our study population,

spiritual healing was also shown to be commonly used among a proportion of the patients in this study, specifically "prayer" and "religious vows". All religions in Lebanon share a common denominator, the incorporation of religion and religious beliefs in daily practices. Where prayer is not only common among the Lebanese population it is an integral part of the Lebanese culture (Ghazeeri *et al*. 2012). Having faith in "God" or "a higher spiritual power", has been suggested to be one of the forms of coping and managing where patients with life-threatening diseases such as breast cancer resort to (Pedersen, Christensen, Jensen and Zachariae 2013). Furthermore, some studies have suggested a positive role of faith and a faith community, for the patients suggest faith may prove an important adjunct to the conventional medical therapies they receive (Lambe 2013).

E. Reasons for CAM Use

The majority of the patients in this study reported using CAM therapies because of their belief of its advantage (91%). This finding indicates and highlights the value of CAM in the Lebanese culture as well as its incorporation in the treatment of cancer patients, by considering it as part of our traditions in this country and the region. In addition to their belief of its advantage, and similar to many studies in the literature done in Korea, Germany, USA, Ghana, and European countries ; 'curing the disease' and 'slowing its progression' as well as 'relief symptoms', 'preventing reoccurrence', 'strengthening the immune system', ' improving emotional and physical well-being' and 'gaining control over ones' health ' are common reasons cited for CAM use among cancer patients in this study (Boon *et al*. 2000; Choi *et al*. 2012; Huebner *et al*. 2014; Kremser *et al*. 2008; Molassiotis *et al*. 2005; Nahleh and Tabbara 2003; Yarney *et al*. 2013). In fact, in a review done, Wancahi *et al*. reported that promoting healing,

improving emotional and physical health, reducing side effects were the main reasons for CAM use among breast cancer patients (Wanchai *et al.* 2010). The numerous reasons behind the use of CAM demonstrate the need of breast cancer patients for coping strategies to support their fight against cancer or symptoms that accompany cancer therapy.

F. Side Effects

Low incidence of significant side effects from CAM use by breast cancer patients was reported by our study participants, this low incidence commensurate with medical literature. For example, in a study done on the prognosis of women with breast cancer after their use of CAM therapies, 3.7 years of follow up, showed that CAM use was found not related to additional breast cancer events (Saquib *et al.* 2011). It is important to note that the true incidence of side effects could easily be underreported in our study for only 10% reported having side effects associated with CAM use. Since the study is a cross-sectional study, with only one patient encounter, the reporting of the side effects is totally dependent on patient subjective assessment. Moreover, the majority of these participating patients take other medications aside from CAM and that could have attributed any side effects they experienced to their standard medication rather than their CAM therapy. It is important to note that the eagerness and determination of some patients to do whatever they can to fight their disease, may have made them willing to accept some side effects and consider it normal and expected in their hope for treatment. Also, the low reported incidence of side effects reflects the perception of CAM users that the CAM therapies used are safe and effective.

G. Differences between CAM Users and Non-Users

In addition to assessing the reasons for CAM use among breast cancer patients, we have explored the reasons for not using CAM among non-users and their acceptability of CAM in the future. Our results indicated that non-users and users of CAM present opposite perception of the value of CAM in the management of breast cancer, as non-users reported that the main reason for not using CAM was the 'lack of belief of CAM benefit' (33.6%). This contrast between users and non-users illustrates the role of belief in patients' behavior and treatment choice. The findings of this study is similar to a study done in Ghana where the major reason for subsiding from CAM cited by the breast cancer patients was 'lack of belief in the efficacy of CAM' (Yarney *et al*. 2013). Other reasons reported in our study for not using CAM was similar to studies done in Europe and Germany where some patients had little information on CAM and thus did not use it (Bairati *et al*. 2005; Molassiotis *et al*. 2005; Tautz, Momm, Hasenburg and Guethlin 2012). Furthermore, as reported by our study one of the profound barriers of CAM use was that participants reported being' afraid from the side effects' associated with CAM, this finding was in accordance with a study done in Ontario, where also one of the main barriers was' fear from harmful side effects' of CAM (Boon *et al*. 2000). Moreover, non-users expressed concern for using a treatment that is not supported and prescribed by their physician and which may possess significant side effects. These findings are in line with previous studies that indicated that patients not using CAM have doubts on the value of CAM and perceive using it as holding a great risk without assurance of benefits especially in the absence of evidence based support (Citrin, Bloom, Grutsch, Mortensen and Lis 2012; Tautz *et al*. 2012).

H. Disclosure of CAM Use to Physician

Physicians and more specifically oncologists are advised to initiate communication with their patients about CAM, emphasizing the effect and promising therapies that are evident based while warning them about harmful therapies that might interfere with their conventional treatment and result in negative side effects. Such a proactive environment between patients and physicians prevents breast cancer patients from enduring side effects and negative interaction of certain CAM therapies and allows a better patient-centered care. This marginal role physician's play in the patients' choice of CAM is further underscored by the fact that the majority of patients surveyed for this study chose not to disclose their CAM use to their physician 72.6%. While only 27.4% disclosed their CAM use to their physician. Furthermore, from our results, patients having a longer duration of breast cancer tend to disclose their use of CAM more than patients with a shorter duration of breast cancer and this could be due to building a good relationship and trust with the treating physician and therefore disclosing their CAM use more freely. Our findings are similar to numerous studies found in the literature where low rate of disclosure were reported. Furthermore, the findings of this study is similar to a recent study done on pediatric leukemia patients in Beirut, Lebanon where less than a third of CAM users disclosed their CAM use to their treating physician (Naja *et al*. 2011). Common findings were also found in Ghana in a study done on breast cancer patients where the majority, 83.3% of CAM users had not informed their doctors about their use of CAM (Yarney *et al*. 2013). A review of the modes of CAM use indicated that around 50% of breast cancer patients did not disclose CAM use to their health care provider (Wanchai *et al*. 2010). In our study, among those that disclosed their CAM use to their physician, 60% discouraged it, only 20% encouraged it and the remaining 20% showed neutral reactions. Several reasons could have influenced such results. First, the

general negative attitude of health care providers towards CAM modalities, also found in our study, this might deter patients from sharing information about their use of CAM. Second, the patient's worrying about losing their physician's trust if they disclose the use of CAM alongside the traditional therapy used. And third, the general belief that CAM products are harmless and they are simple vitamins or immune stimulants or herbs that are commonly used in fighting the disease without affecting the conventional treatment. Similar to our findings a systematic review done on 21 studies that explored the communication among cancer patients and their treating physician showed that a range between 20-77% of the patients did not disclose their use of CAM to the physician. The main reasons for non-disclosure were also similar to our study, that the 'doctors lack of inquiry', 'patient's anticipation of the doctor's disapproval', 'disinterest', or 'inability to help' and 'patient's perception that disclosure of CAM use is irrelevant to their conventional care' (Davis, Oh, Butow, Mullan and Clarke 2012).The low disclosure rate and lack of communication towards the physician found in this study is worrisome and warrants further investigation. Since poor communication between patients and physicians threatens the safety, prognosis of the disease and the overall the well-being of the patient therefore it is very important to improve the patient-doctor communication towards CAM use. Since improving and encouraging communication towards the treating physician, ensures that patients will receive reliable information regarding different CAM modalities, their efficacy and possible side effects.

CHAPTER V

SUMMARY CONCLUSION AND RECOMMENDATION

A. Strength and Limitations of This Study

To date, this study is the first to report, the prevalence, types, modes and determinants of CAM use among Lebanese breast cancer patients. The socio-demographic predictors of CAM usage were also investigated in our study.

There are a couple of limitations in this study that should be considered. First, a selection bias might have jeopardized the representativeness of the sample population and the external validity of the results. The study populations were collected from two medical institutions in Beirut, and therefore the results may not be generalized to all breast cancer patients in Lebanon. However it is worth mentioning that the selection of two medical centers, one major academic medical center and a private philanthropic medical center enhanced the representation of various socio-demographic groups. Our patient's population mean age is 53 years which is very similar to the mean age of breast cancer patients in Lebanon (Lakkis, Adib, Osman, Musharafieh and Hamadeh 2010). Almost two third of patients were recruited from the larger academic medical center, reflecting the volume of patients seen in each center. This observation that almost 40% of participants were diagnosed with breast cancer less than a year ago, 36% diagnosed in 1-5 years and only 24% diagnosed more than 5 years ago, is secondary to the fact that patients diagnosed within the previous year undergo a closer follow up and are more likely to be receiving a conventional treatment for breast cancer, chemotherapy and therefore be recruited in this survey. To minimize the selection bias, efforts were made to include patients receiving chemotherapy as well as outpatients, being at an early and

advanced stage of the disease. Second, patients might have experienced the social desirability bias. Since data collection was conducted on patients awaiting their doctors' appointments in the clinics waiting areas. Although patients were surveyed and asked about their habits and opinions in private clinics and were assured complete confidentiality of their responses, it cannot be guaranteed that patients did not alter their answers to satisfy their health care providers. Third, the results might have underestimated the rate of CAM use prevalence among breast cancer patients since all patients were recruited from hospital clinics while visiting their physicians. This might have resulted in a bias towards conventional therapy. Moreover, the disclosure rate on CAM use was only found to be 27%, indicating the possibility that the fear of censure would make patients avoid reporting the use of CAM therapies. And finally, although CAM was clearly and extensively defined for every study participant prior each interview, some patients might not consider some complementary modalities as part of CAM.

B. Summary

Additionally, this study shows that the use of CAM therapies is prevalent among Lebanese breast cancer patients, with biological based therapies being most commonly used. Our findings are similar to studies done in the region and around the world where younger patients and those with a more advanced stage of the disease were more likely to use a form of CAM. Patients mainly relied on family and the media for their choice of CAM. Physician's role in orienting CAM use in our study population was minimal and CAM users were less likely to disclose their use of CAM to their treating physician. This indicates that patients could be unaware of the possible side effects that might accompany CAM use on their breast cancer treatment and prognosis. The high

use of CAM therapies among Lebanese breast cancer patients, with a poor communication with the treating physician on the disclosure of CAM use could likely jeopardize the health and well-being of patients. And although CAM nowadays is still not incorporated into conventional treatment, many breast cancer patients are incorporating different CAM therapies along with conventional therapy rather than in place of it. The problem facing these patients is the poor communication and disclosure of these patients on CAM use to their treating physician (Chang, Wallis and Tiralongo 2007). Physicians are recommended to maintain a proactive attitude, encourage open communication, initiate discussion on CAM use and constantly showing respect towards patients' decision-making power on this matter. CAM practitioners and advertisements on the media should be regulated so that patients would not be deluded since many non-evident CAM therapies are being promoted in a very appealing and convincing way. Moreover, a coordinated approach among stakeholders including the Ministry of Health, professional bodies, academic institutions and healthcare facilities is necessary to initiate a policy disclosure on the means to enhance public awareness and integrate CAM into the education, training and professional development programs of health care professionals, as well as enhance cancer patients' awareness on safe and rational use of CAM therapies.

APPENDIX I

ETHICAL APPROVAL LETTER FORM FROM THE INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES AT THE AMERICAN UNIVERSITY OF BEIRUT

AUB American University of Beirut الجامعة الأميركية في بيروت Institutional Review Board | لجنة الأخلاقيات www.aub.edu.lb

APPROVAL OF RESEARCH AMMENDMENT

September 11, 2013

Dr. Farah Naja
American University of Beirut
01-350000 ext 4504
fn14@aub.edu.lb

Dear Dr. Naja,

On September 11, 2013, the IRB reviewed the following protocol:

Type of Review:	Modification, Expedited
Project Title:	Prevalence and determinants of the use of complementary and alternative medicine among breast cancer patients
Investigator:	Farah Naja
IRB ID:	NUT.FN.11
Funding source:	None
Documents reviewed:	Letter received September 9, 2013, amended: IRB application, proposal, English and Arabic versions of the consent documents (versions received September 9, 2013), diet questionnaire (English and Arabic versions received September 9, 2013), 24 hour dietary recall (English and Arabic versions received September 9, 2013), and the manual for calculation of diet adherences scores.

The IRB approved adding a secondary objective to this study to investigate the adherence to the Mediterranean diet in breast cancer patients from September 11, 2013 to June 13, 2014 inclusive. Before April 13,2014 or within 30 days of study close, whichever is earlier, you are to submit a completed "FORM: Continuing Review Progress Report" and required attachments to request continuing approval or study closure.

If continuing review approval is not granted before the expiration date of June 13, 2014 approval of this research expires on that date.

Please find attached the stamped approved documents:

1. Proposal (version received September 9, 2013),
2. English and Arabic versions of the consent documents (version received September 9, 2013),
3. Diet questionnaire (English and Arabic versions received September 9, 2013),
4. 24 hour dietary recall (English and Arabic versions received September 9, 2013),
5. The manual for calculation of diet adherences scores (version received September 9, 2013).

Kindly, use copies of these documents to document consent.

Thank you

Beirut PO Box 11-0236 (FI5), Riad El Solh 1107 2020, Beirut, Lebanon | Tel: +961-1-350000 Ext: 5445 | Fax: +961-1-738025 | Email: irb@aub.edu.lb
New York 3 Dag Hammarskjold Plaza, 8th Floor | New York, NY 10017-2303, USA | Tel: +1-212-583-7600 | Fax: +1-212-583-7651

The American University of Beirut and its Institutional Review Board, under the institution's Federal Wide Assurance with OHRP, comply with the Department of Health and Human Services (DHHS) Code of Federal Regulations for the Protection of Human Subjects ("The Common Rule") 45CFR46, subparts A, B, C, and D, with 21CFR56; and operate in a manner consistent with the Belmont report, FDA guidance, Good Clinical Practices under the ICH guidelines, and applicable national/local regulations.

Sincerely,

Michael Clinton, PhD
IRB Vice Chairperson
Social & Behavioral Sciences

Cc: Fuad Ziyadeh, MD, FACP, FASN
Professor of Medicine and Biochemistry
Chairperson of the IRB

Ali K. Abu-Alfa, MD, FASN
Professor of Medicine
Director, Human Research Protection Program

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APPENIDX II

CONSENT FORM

Prevalence and Determinants of the use of complementary and alternative medicine (CAM) among Breast Cancer Patients in Lebanon

Consent Form

Investigator: Dr. Farah Naja
Address: American University of Beirut (AUB)- Hamra-Beirut, Lebanon
Phone: 01-350000 (ext. 4504)
Setting: Basile Cancer Institute at AUBMC

You are being asked to participate in a research study conducted at the American University of Beirut-Medical Center. Please take time to read the following information carefully before you decide whether you want to take part in this study or not. Feel free to ask us if you need more information or clarification about what is stated in this form and the study as a whole.
The main objective of this study is to assess the prevalence, determinants, modes of use and disclosure to physicians of Complementary and Alternative Medicine (CAM) among breast cancer patients in Lebanon and to assess the adherence of your dietary intake to the Mediterranean diet.

You are eligible for our research study only if you are of Lebanese nationality, report a diagnosis of breast cancer for a minimum of 2 months prior to the study, and are attending the Basile Cancer Institute at AUBMC for breast cancer treatment or the Makassed General Hospital (MGH). The charge nurse will introduce the study for the patients, after which the research assistant will approach the patients, further explain the study and obtain consent from interested participants for the interview and data collection to follow.
If you are eligible for this study and agree to be a participant, you are asked to complete a survey questionnaire about socio demographic factors such as age, sex, marital status, household income, educational level, symptoms and treatment of of breast cancer, and the type and frequency of complementary and alternative medicine use as well as a diet questionnaire and one a 24-hour recall. A total of 377 breast cancer patients will be recruited for inclusion in this study. The survey needs around 15 minutes to be conducted. The timing of the interview (whether before, after or during the treatment) will be decided by the patient, in a way not to compromise nor delay the medical care and to ensure that the patient is not in a state of discomfort because of the medical treatment.

Your participation in this survey questionnaire is completely voluntary but it is very important to us. If you agree to be part of our study you will be helping us find out the prevalence and the determinants of complementary and alternative medicine use among Lebanese breast cancer patients.

There are no other expected risks to you for helping us with this study. There are also no expected benefits for you either. There will be no loss in health services benefits in case patient refuses to participate and that the participant can stop answering questions at any point in time or refuse to answer any question.

If you agree to participate in this research study, the information will be kept confidential under lock and key. The researcher will not share the patient information with the health care provider. Also, the researcher will not have access to the participant medical records. All information will be collected

anonymously (i.e.: with no name); however, a code on the questionnaire could be linked to the consent form and only the principal investigator has access to that link.

In case of any adverse event as a result of the study, there will be no compensation to cover such expenses.

Investigator's Statement:

I have reviewed, in detail, the informed consent document for this research study with _____ _____ (name of patient) the purpose of the study and its risks and benefits. I have answered to all the patient's questions clearly.

I will inform the participant in case of any changes to the research study.

_____ _____
Name of Investigator or designee Signature

_____ _____
Date Time

Patient's Participation:

I have read and understood all aspects of the research study and all my questions have been answered. I voluntarily agree to be a part of this research study and I know that I can contact Dr. Farah Naja at 01-350 000 ext. 4504 or any of his/her designee involved in the study in case of any questions. If I feel that my questions have not been answered, I can contact the Institutional Review Board for human rights at 01-350 000 ext. 5443. I understand that I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form, and it will not affect my care or benefits. I know that I will receive a copy of this signed informed consent.

_____ _____
Name of Patient Signature

_____ _____
Date Time

_____ _____
Witness's Name Witness's Signature
(If patient, representative or parent do not read or is visually impaired)

_____ _____
Date Time

Would you allow us to contact you for future research?
□ Yes □ No
If yes, please provide us with your phone number: _____

APPENDIX III

EXAMPLES OF THE DIFFERENT CAM MODALITIES

Examples of the different CAM modalities reported such as 'Special foods', 'Dietary supplements' are the following:

Special foods:

Honey
Black sees
Camel milk
Soy
Pomegranate
Ginger

Dietary supplements:

Prebiotics
Graviola pills

Herbal teas:

Zhourat
Green tea

Spiritual healing: religion-specific practices

Prayers
Lighting candles
Pledging specific vows
Consumption of foods deemed to be holly such as ‘Zamzam water’ (a holly water for Muslims, brought from Mecca)
Fasting (abstinence from any food or drink from dawn to sunset)

Vitamin and minerals:

Multi-vitamins
Iron pills

Folk medicine:

Bloodletting
Cupping

Other:

Aroma therapy
Inhalation of Cannabis 'Hashishi'
Intake of shark cartilage

APPENDIX IV

QUESTIONNAIRE ENGLISH AND ARABIC

Prevalence and Determinants of Complementary and Alternative Medicine Use among Breast Cancer Patients in Lebanon

Date (dd/mm/yy) ___/___/___
Subject ID:_____

Section A: Socio-demographics

1- **Age (years):_____**

2- **Place of residence: _____**

3- **Marital status:**

a- Single (not married, separated, widowed, divorced)
b- Married/living with a partner

4- **Monthly household income**

a-<500$
b-500- 1000$
c-1000-2000 $
d->2000$

5- **Highest education level attained**

a- Illiterate
b- Primary
c- Secondary School
d- Diploma; Bachelor Degree
e- Masters, Doctoral

6- **Employment status**

a- Employed
b- Retired
c- Housewife
d- Unemployed
e- Other: _____

7- **Current occupation: _____**

8- **Number of rooms (except for toilet, kitchen, balcony& garage) in the household: _____**

9- **Number of persons (except for newborns) in the household: _____**

10- **Health insurance by type**
- a- Public (Ministry of Health)
- b- Social (NSSF, COOP, Army, Public Security)
- c- Private
- d- Self-paying

Section B: Breast Cancer

11- How long have you been diagnosed with breast cancer? _____ 1 year.

12- What is your current status of breast Cancer?
- a- Metastatic
- b- Locally advanced
- c- Early stage

13- Site of metastasis (if present):_____

14- Do you have a Family history of breast cancer?
- a- Yes, relation to patient:_____
- b- No

15- Do you have a Family history of other Cancers?
- a- Yes, please specify _____
- b-No

16- Do you suffer from any other health condition?
- a- Hypertension
- b- Cardiovascular disease
- c- Obstructive pulmonary disease
- d- Others:

17- Do you adhere to your doctor's recommendations?
- a- Yes
- b- No

18- What are the main barriers to your adherence to the recommendations?

- a- Unaffordable medication

b- Intolerance of drug side effects
c- others, please specify _____

19- Have you received any dietary advice since you have been diagnosed?
a- Yes
b- No

20- If yes, from whom did you receive the dietary advice?
a- Doctor
b- Nurse
c- Dietitian
i. Referral
ii. Personal decision

21- What symptoms do you have? (circle all that applies)
a- Fatigue
b- Pain
c- Appetite loss
d- Early satiety
e- Weight loss
f- Dry mouth
g- Constipation
h- Taste changes
i- Dysphagia
j- Nausea
k- Vomiting
l- Urinary symptoms
m- Bleeding
n- Hoarseness
o- Skin symptoms
p- Cough
q- Sore mouth
r- Dyspnea
s- Other: _____

22- What is the most distressing symptom among those you have? _____

23- Your current state of health
a- Very poor
b- Poor
c- Fair

d- Good
e- Excellent

Section C: CAM use

24- Have you used CAM since your diagnosis with breast cancer?
a- Yes
b- No

25- Have you used CAM in the previous year?
a- Yes
b- No

26- Are you using CAM as alternative or as complementary to the conventional treatment?
a- Alternative
b- Complementary

27- Are you using CAM as treatment or relief from symptoms?
a- Treatment of breast cancer
b- As relief of symptoms and prevention of suffering

28- If you have not used CAM, would you consider using it in the future?
a- Yes
b- No

29- If you have not used CAM, why not?
a- I never heard of it
b- I'm afraid of the side effects
c- I don't believe in it
d- The doctor didn't prescribe it
e- Not to have additional burden
f- Other, please specify.....

30- Have you asked your doctor about the CAM product you used?
a- Yes
b- No

31- If YES, what was his reaction?
a- Encouraging
b- Discouraging
c- Neutral

32- What type of CAM product have you used?
- a- Vitamins/Minerals
- b- Dietary supplements or (Special foods)
- c- Herbal remedies/Herbal preparations, specify:
- d- Spiritual healing
- e- Folk medicine
- f- Other, please specify……:

33- How did you choose your CAM?
- a- Personal choice
- b- Friends
- c- Media (Internet, magazines, TV)
- d- Health practitioner
- e- Family beliefs
- f- Health food shop
- g- alternative therapist

34- How often do you use CAM?
- a- One time
- b- Regular (2 or more per week for a minimum of a month)
- c- Once per month
- d- Other

35- Who provided you with the CAM treatment?
- a- Massage therapist
- b- Acupuncturist
- c- Practitioner of traditional medicine
- d- Naturopath
- e- Homeopath
- f- Got it from a local store or pharmacy.

36- If the use of CAM was regular, what is the estimated cost per month?
- a- < $10
- b- $11 – 20
- c- $21 – 30
- d- $31 – 40
- e- $41 – 50
- f- >$50

37- Why have you used CAM? (circle all that applies)
- a- To manage cancer complications/progression
- b- To reduce the side effects/symptoms of conventional treatment
- c- To help in relaxation and feeling better psychologically

d- To improve your general health and ensure long term survival
e- To feel more in control over your health care
f- To get relieved from sorcery spell
g- To provide energy
h- Disappointment from conventional medical therapy
i- Feeling of having no alternative
j- Belief in advantages of CAM practices
k- Family tradition/ Culture
l- It is more natural
m- Curiosity
n- Other, please specify:_____

38- In general, how much did CAM help you?
a- Not at all
b- Some
c- A lot, very satisfied
d- You can't tell

39- Have you suffered from any side effect from CAM?
a- Yes
b- No
c- undecided

if yes please specify _____

40- Would you use CAM again?
a- Yes
b- No
c- undecided

41- Will you recommend the use of this CAM to other breast cancer patients?
a- Yes
b- No
c- Undecided

Thank you very much

انتشار استخدام المتممات والبدائل الطبية لدى مرضى سرطان الثدي في لبنان

وثيقة موافقة المشاركة في الدراسة

الباحث: د. فرح نجا
العنوان: الجامعة الاميركية في بيروت- حمرا - بيروت- لبنان
هاتف: 01-350000 (قسم 4504)
مقر إجراء البحث: مركز باسيل للأورام السرطانية في مستشفى الجامعة الاميركية في بيروت

المطلوب منكم المشاركة بدراسة في المركز الطبي في الجامعة الاميركية في بيروت. يرجى أخذ الوقت الكافي لقراءة المعلومات التالية بعناية قبل أن تقرر ما إذا كنت ترغب في المشاركة في هذه الدراسة أم لا .لا تتردد في الطلب اذا كنت بحاجة الى مزيد من المعلومات أو توضيح حول ما ورد في هذا النموذج وهذه الدراسة ككل.

تهدف هذه الدراسة إلى معرفة مدى انتشار واستخدام المتممات والبدائل الطبية لدى مرضى سرطان الثدي في لبنان وتقييم نسبة الالتزام بحميات البحر الأبيض المتوسط (Mediterranean Diet).

يحق لك المشاركة في هذه الدراسة إن كنت لبنانيا، وتشتكي/ن من مرض سرطان الثدي منذ مدة لا تقل عن الشهرين قبل هذه الدراسة وتعالج حاليا في مركز باسيل للأورام السرطانية في مستشفى الجامعة الاميركية لعلاج سرطان الثـــدي أو مستشفى المقاصد في بيروت.

لقد أطلعتـــك الممرضة المسؤولةعلى هذه الدراسة مما سمح الباحث بالإقتراب منك لمناقشة ما إذا كنت مهتم بالمشاركة في هذه الدراسة. في حال الموافقة على المشاركة، سوف تملأ استمارة عن وضعك الاجتماعي مثل العمر، الجنس، الوضع العائلي، الدخل السنوي، المستوى التعليمي الخ ،عوارض وعلاج مرض سرطان الثدي، ونوع المتممات والبدائل الطبية وتواتر استخدامها وكذلك عن استهلاكك الغذائي من خلال إستمارة ومراجعة المحصول الغذائي خلال ال٢٤ الساعة الماضية.

. سيتم ادراج مجموع 377 من مرضى سرطان الثدي لادخالهم في هذه الدراسة. يتطلّب ملء الاستمارة حوالي ال15دقائق. سيتم تحديد وقت المقابلة (سواء قبل، بعد أو أثناء فترة العلاج) من قبل المريض، بطريقة لا تؤثر أو تؤخر الرعاية الطبية و للتأكد أن المريض ليس في حالة من الانزعاج جراء العلاج.

إن مشاركتكم في هذه الدراسة طوعية تماما، ولكنها مهمة جدا بالنسبة لنا .اذا كنت توافق على أن تكون جزءا من دراستنا سوف تساعدنا على معرفة مدى انتشار واستخدام المتممات والبدائل الطبية لدى مرضى سرطان الثدي في لبنان.

إن مشاركتكم في هذا البحث خالية من المخاطر والمكتسبات الشخصية. الرجاء أخذ العلم بأن عدم المشاركة لن يؤثر سلباً على منافعك الشخصية. في حل رفض المريض المشاركة في هذه الدراسة، لن يفقد أي من الخدمات الصحية. بالاضافة. يمكن للمشارك التوقف عن الإجابة على الأسئلة في أي وقت وكذلك يمكنه رفض إجابة أي سؤال.

نريد أن نؤكد على السرية التامة في الدراسة وأن جميع المعلومات و إمضاء كل من المشارك والشاهد في هذه الدراسة ستحفظ في خزانة مقفلة بالمفتاح وستستعمل لهدف علمي فقط. إن الباحث لا يشارك أو يكشف أية معلومات عن المريض مع الطبيب. أيضا، إن الباحث لا يستطيع الحصول على سجلات المريض الطبية. بالإضافة، سيتم جمع جميع المعلومات بشكل مجهول (أي عدم وجود الاسم على الإستمارة). ومع ذلك، يمكن ربط رقم المشترك على الاستمارة بوثيقة الموافقة للمشاركة في هذه الدراسة مع العلم أن الباحث الرئيسي فقط يملك هذا الرابط.

في حال حدوث اي شيء سلبي جراء هذه الدراسة، لن يكون هناك تعويضات لتغطية هذه النفقات.

وثيقة الباحث:

لقد راجعت وبالتفصيل مع ----------(اسم المشترك) وثيقة المشاركة في الدراسة هذه واهدافها والمكاسب و المخاطر التي قد تنتج عنها. قمت بالاجابة على كافة الاسئلة و سوف ابلغ المشترك باي تغيير قد يطرأ على هذا البحث العلمي.

الإسم الباحث: ..... الإمضاء: .....

التّاريخ: ..... الوقت : .....

وثيقة الموافقة:

لقد قرأت كل المعلومات التي قدمت عن هذه الدّراسة و تمت الإجابة عن جميع أسئلتي المتعلّقة بها. انا اوافق طوعا للمشاركة في هذه الدراسة و أفهم أنّه بإمكاني التوجّه مباشرة بأي سؤال أواستفسار حيال أي جانب من هذا البحث إلى د. فرح نجا على 01-350000 مقسم 4504 او اي شخص متعلق بالدراسة. أفهم تماما أنّه بإمكاني اكتساب معلومات إضافيّة حيال حقوقي في هذه الدراسة من قبل مجلس المراجعة المؤسسية لحقوق الانسان على الرقم 01-350000 مقسم 5443.

الإسم: ..... الإمضاء: .....

التّاريخ: ..... الوقت : .....

الشاهد: ..... الإمضاء: .....

(اذا المريض، او ممثل المريض او والد/ة المريض لا يقرأ/تقرأ أو ضعيف البصر)

التّاريخ: ..... الوقت : .....

☒ هل تسمح لنا بالاتصال بك للبحوث المستقبلية؟

☐ نعم ☐ لا

اذا كانت الإجابة نعم، يرجى تزويدنا برقم هاتفك

مع الشكر الجزيل،

العوامل المؤثرة لاستعمال المتممات والبدائل الطبية والعادات الغذائية لدى المصابين بسرطان الثدي في لبنان
استمارة

تاريخ: (يوم/شهر/سنة): _____
رقم المشترك: _____

SECTION A: DEMOGRAGHICS

1. العمر (سنة):_____

2. مكان الاقامة:_____

3. الوضع العائلي:
❑ أعزب (غير متزوج، منفصل ، مطلق ، أرمل)
❑ متأهل، مقيم مع الشريك

4. الدخل الشهري:
❑ $500 >
❑ $1000-$500
❑ $2000-$1000
❑ $2000 <

5. المستوى العلمي:
❑ أمي
❑ مدرسي-ابتدائي
❑ مدرسي-ثانوي
❑ جامعي- بكالوريوس
❑ جامعي: دراسات عليا

6. الوضع المهني:
❑ موظفة
❑ متقاعدة
❑ ربة منزل
❑ عاطلة عن العمل
❑ غيره:_____

7. المهنة الحالية: _____

8. عدد الغرف في المنزل(باستثناء الحمام، المطبخ، الشرفة،الكاراج): _____

9. عدد أفراد الأسرة (باستثناء حديثي الولادة): _____

10. نوع التأمين:

❑ وزارة الصحة
❑ ضمان/تعاونية/الجيش/الأمن العام
❑ خاص
❑ حساب خاص

SECTION B: Breast Cancer

11. كم مضى على معرفتك بأنك مصاب بسرطان الثدي ؟ _____

12. ما هي مرحلة مرض سرطان الثدي؟
- ❑ منتشر
- ❑ موضعي
- ❑ في المرحلة الأولى

13. موضع انتشار الورم،اذا وجد ؟ _____

14. هل لديك تاريخ عائلي لمرض سرطان الثدي؟
- ❑ نعم ،صلة القرابة للمريض:_____
- ❑ لا

15. هل لديك تاريخ عائلي لأمراض سرطانية أخرى؟
- ❑ نعم، حدد:_____
- ❑ لا

16. هل تعاني من أي عوارض صحية أخرى؟
- ❑ ضغط الدم المرتفع
- ❑ أمراض القلب و الشرايين
- ❑ مرض رئوي
- ❑ غيره حدد: _____

17. هل تتبع تعاليم/نصائح الطبيب؟
- ❑ نعم
- ❑ لا

18. ما هي العوائق الرئيسية التي تحول دون اتباع نصائح الطبيب؟
- ❑ علاج مكلف ماديا
- ❑ عدم القدرة على تحمل العوارض الجانبية
- ❑ غيره. حدد:_____

19. هل حصلت على نصائح غذائية منذ تشخيصك بسرطان الثدي؟
- ❑ نعم
- ❑ لا

20. اذا نعم ، ممن حصلت على هذه النصائح الغذائية؟
- ❑ الطبيب
- ❑ الممرضة
- ❑ أخصائية التغذية
  - o تم تحويلك
  - o قرار شخصي

21. أي من هذه العوارض تعاني؟

- ❑ التعب/ الارهاق
- ❑ الألم
- ❑ خسارة الشهية
- ❑ الشبع المبكر
- ❑ خسارة الوزن
- ❑ جفاف في الفم
- ❑ تغييرات في حاسة التذوق
- ❑ صعوبة في البلع
- ❑ الامساك
- ❑ الغثيان
- ❑ تقيؤ
- ❑ اسهال
- ❑ عوارض في المسالك البولية
- ❑ نزيف
- ❑ بحة في الصوت
- ❑ عوارض في الجلد
- ❑ سعال
- ❑ فم ملتهب
- ❑ ضيق التنفس

22. ما هو العارض الأكثر ازعاجا؟_____

23. كيف تصف حالتك الصحية الآن؟

- ❑رديئة جدا
- ❑ رديئة
- ❑ وسط
- ❑جيدة
- ❑ ممتازة

SECTION C: CAM Use

24. هل استخدمت المتممات والبدائل الطبية بعد تشخيصك بسرطان الثدي؟

- ❑ نعم
- ❑لا

لا

25. هل استخدمت المتممات والبدائل الطبية خلال السنة الماضية؟

- ❑ نعم
- ❑لا

26. هل تستخدم المتممات و البدائل الطبية كعلاج بديل أو كمكمل للعلاج التقليدي؟

- ❑ علاج بديل
- ❑ مكمل للعلاج التقليدي

27. هل تستخدم المتممات و البدائل الطبية لعلاج سرطان الثدي أو لتخفيف العوارض؟

- ❑ علاج لسرطان الثدي

❑ لتخفيف العوارض

28. اذا لم تستخدم المتممات و البدائل الطبية بعد، هل تفكر في استخدامها في المستقبل؟
❑ نعم
❑ لا

29. اذا لم تستخدم المتممات و البدائل الطبية ، ما هو السبب؟
1. لم أسمع بها
2. أخشى من العوارض السلبية
3. لا أؤمن بها
4. لم يصفها الطبيب
5. لنها تشكل عباً اضافياً
6. اخرى، حدد _____

30. هل استشرت الطبيب عن استخدام المتممات و البدائل الطبية؟
❑ نعم
❑ لا

31. اذا كان الجواب نعم، ما كانت ردة فعله؟
❑ مشجعة
❑ غير مشجعة
❑ لم يبد رأياً

32. ما هو نوع المتمم/البديل الطبي الذي استخدمته؟
❑ الفيتامينات و المعادن
❑ متممات غذائية
❑ أعشاب، حدد _____
❑ علاج روحي
❑ علاج شعبي
❑ غيره. حدد _____

33. كيف اخترت المتممات والبدائل الطبية؟ (أشر الى كل الإجابات المناسبة)
❑ خيار شخصي
❑ صديق
❑ وسائل الاعلام (التلفزيون/المجلة/الانترنت)
❑ معتقدات عائلية
❑ متاجر الأغذية الصحية
❑ معالج بالطب البديل
❑ اخرى، حدد _____

34. كم مرة تستخدم المتممات و البدائل الطبية؟
❑ مرة
❑ بانتظام (مرتين أو أكثر في الأسبوع لمدة شهر على الأقل)
❑ مرة في الشهر
❑ غيره، حدد _____

35.من أين حصلت على المتمم والبديل الطبي؟

- ❑ أخصائي تدليك
- ❑ أخصائي في العلاج بالوخز
- ❑ معالج في الطب التقليدي
- ❑ معالج طبيعي
- ❑ متجر أو صيدلية

36. بالمعدل كم تصرف شهرياً على استعمال المتممات والبدائل الطبية؟

- ❑ $10<
- ❑ $20-11
- ❑ $30-21
- ❑ $40-31
- ❑ $50-41
- ❑ $50<

37.لماذا لجأت الى المتممات والبدائل الطبية ؟ (أشر الى كل الإجابات المناسبة)

- ❑ للتحكم في سرطان الثدي
- ❑ للتخفيف من العوارض الجانبية للعلاج التقليدي
- ❑ لتحسين الوضع النفسي
- ❑ لتحسين الوضع الصحي العام واطالة البقاء
- ❑ للاحساس في السيطرة على حالتي الصحية
- ❑ للتخلص من الشعوذة
- ❑ خيبة أمل من العلاج التقليدي
- ❑ لا خيار اخر
- ❑ لمنافع المتممات والبدائل الطبية
- ❑ تقاليد عائلية
- ❑ لأنها مكونات طبيعية
- ❑ بدافع الحشرية
- ❑ اخرى، حدد_____

38.ما هو شعورك بعد استخدام المتممات والبدائل الطبية؟

- ❑ زيادة في الطاقة
- ❑ تحسن في الوضع النفسي
- ❑ تخفيف من العوارض
- ❑ تحسن في الوضع الجسدي
- ❑ تدهور في الوضع النفسي
- ❑ زيادة في العوارض
- ❑ لا تغيير
- ❑ غيره. حدد_____

39.بشكل عام، الى أي مدى ساعدك استخدام المتممات والبدائل الطبية؟

- ❑ أبدا
- ❑ قليلا

❑ كثيرا
❑ لا أعرف

40. هل واجهت أى عوارض سلبية بعد استخدام المتممات و البدائل الطبية؟
❑ نعم
❑ لا
❑ لا أعرف
❑ اذا نعم ، حدد _____

41. هل تعيد استخدام المتممات و البدائل الطبية مرة أخرى؟
❑ نعم
❑ لا
❑ لا أعرف

42. هل تنصح باستخدام المتممات و البدائل الطبية لمرضى سرطان الثدي؟

❑ نعم
❑ لا
❑ لا أعرف

شكراً لتعاونكم ووقتكم

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