

Can the use of Reflexology for symptom relief in Breast Cancer patients improve their Quality of Life?

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Chapter 1.

Abstract.

Aims:

- To determine whether or not the use of reflexology can improve Quality of Life (QOL) in breast cancer patients during and after treatment (Chemotherapy).
- To raise awareness with regards to the effectiveness of reflexology.
- To highlight the pros and cons of making reflexology readily available on the NHS.

Sample.

5 retrieved studies, including 3 Randomised Control Trial's (RCT's), 1 Systematic Review and 1 Quasi-Experimental study, each of varying sample sizes/origins/methodological quality.

Methods.

A Systematic Review was conducted using three major online databases including PubMed, The Cochrane Library and Cancer Nursing (Online Journal). The search terms "Reflexology, breast cancer and QOL" were used.

Results.

5 studies meeting inclusion criteria were included in the Systematic Review, including grey literature, 3 RCT's were retrieved, 1 quasi-experimental study and 1 systematic review. Studies varied with regards to methodological quality. All 5 studies suggested benefits in using reflexology for improving QOL in breast cancer patients.

Conclusion.

No firm conclusion can be made regarding the benefits of reflexology for improving QOL in breast cancer patients. However, included studies suggest that benefits and effectiveness of reflexology in improving QOL do exist, and should therefore be considered. More scientific research needs to be conducted in this area.

Implications for current practice and future research.

More scientifically correct research needs to be conducted regarding this topic. In addition to this, improvements need to be made to the existing studies that are already available. Results of this dissertation may be considered by medical healthcare professionals as well as breast cancer patients, and enable them to explore the options of using reflexology to improve QOL.

Chapter 2.

Introduction/ Rationale.

Breast cancer is the most common type of cancer in the UK, accounting for a significant 30% of all new cases in females, since 1997, (Cancer Research UK, 2014a). Fortunately, more than 64% of patients who have been diagnosed are now expected to live for more than 20 years thanks to early detection, due to the UK breast screening programme, and effective treatments such as radiotherapy and chemotherapy, (Cancer Research UK , 2014b). Chemotherapy uses cytotoxic drugs to destroy cancer cells, disrupting the way they grow and divide, which can be very effective. Unfortunately, chemotherapy can also destroy normal, vital cells, which can lead to numerous side effects, (Macmillan, 2012). Side effects of the chemotherapy drug can vary from patient to patient, but many patients suffer from risk of infection, sickness, tiredness, diarrhoea, loss of appetite/taste buds, hair loss and depression, (Cancer Research, UK, 2014c). These side effects can severely reduce a cancer patient's quality of life and their ability to carry out daily activities. Perry et al, (2007) cite that "Breast cancer patients experience physical symptoms and psychological distress that adversely affect their quality of life (QOL)". A reduced QOL can potentially reduce a breast cancer patient's chances of overcoming the disease due to the fact that "many patients are unable to complete their chemotherapy or radiation treatments simply because they can't tolerate the difficult side effects", (Labriola, 2000, p.3). It is therefore vital that further investigations into treatments that can reduce side effects are carried out in an attempt to improve QOL.

Furthermore, mainstream (conventional) health care providers rarely treat these side effects through using complementary therapies such as reflexology, due to the fact

that they are unfamiliar with these sorts of treatments and that many are unproven, (Labriola, 2000, p.2). Various medications are often prescribed to help a patient deal with the side effects of chemotherapy such as pain killers, anti-depressants and anti-sickness tablets, (Macmillan, 2012). However these medications can also present a cancer patient with further unwanted side effects, and can potentially further reduce their QOL. Pain killers for example are prescribed to patients suffering from painful side effects of chemotherapy, or to help reduce the pain caused by the cancer itself. Although these painkillers, such as Co-codamol's can improve QOL in the short term by alleviating painful symptoms, they can also cause a variety of side effects in the long term such as constipation and dizziness (NHS, 2014). It can therefore be seen that although vital, conventional medication to treat side effects can also reduce a cancer patients QOL.

It is believed that the concept of reflexology as a medical treatment emerged in western ideas during the 19th century, on the discovery that one could influence health and well-being through reflex actions, (Kunz, 2003, p.13). The concept of reflexology works on the "Zone theory" where it is believed that the body can be divided into longitudinal zones, running from the head to the toes, and that all of these zones are connected. Stimulation at one part of these zones in the feet, or hands can restore equilibrium to the entire body, (Kunz, 2003, p.14). Research suggests that the complementary therapy reflexology could therefore be beneficial to patients who suffer with breast cancer.

Kunz, (2003,p.26) claims that Reflexology can help a patient to relax, cope with stress, relieve pain, uplift mood and improve general wellbeing, thus improving QOL. In addition to this Kunz (2003, p.26) cites that reflexology offers a "natural, drug free treatment option, and offers a non-intrusive way of expressing love or care for

someone, benefiting the giver and recipient alike” and thus an appealing option for those patients inundated with drugs and medication. A study conducted by Yang, (2005) concludes that the use of reflexology was effective in reducing nausea, vomiting and fatigue in breast cancer patients in the experimental groups compared to the controlled groups. This study conducted by Yang (2005) therefore supports the fact that the use of reflexology for improved QOL in breast cancer patients can be successful and will therefore provide a worthwhile topic to look into. In addition to this, there is currently very little scientific evidence to prove that reflexology can provide symptom relief and improve QOL in breast cancer patients, (Cancer Research UK, 2014a). It would therefore be further beneficial to conduct more research into this area of study, in order to add to the current literature available, and build a positive case for the use of reflexology in breast cancer patients.

The main aim of this dissertation project will be to determine whether or not the use of reflexology really can improve QOL in breast cancer patients, during, and after treatment. In addition to this, my hopes are to raise awareness with regards to the effectiveness of reflexology in order to broaden patient's options and opinions.

Through completion of this dissertation I further aim to highlight the pros and cons of making reflexology for breast cancer patients readily available on the NHS to cancer patients. Currently, primary care organisations have specific policies with regards to the extent of which their patients can have access to complementary and alternative medicine, including reflexology. It is the GP's / Oncologist's decision as to whether or not a patient will benefit from receiving reflexology. (NHS careers, n/d) However, as previously stated, conventional health care providers rarely sign post towards complementary and alternative medicine, due to being unfamiliar with them and even regarding some as dangerous. Through completion of my dissertation

I therefore also hope to expand a reader's understanding and knowledge of reflexology.

Participants for this dissertation project will include breast cancer patients of all ages, due to the fact that breast cancer is the most common type of cancer in the UK, (Cancer Research UK, 2014a). As previously stated, over 64% of breast cancer patients are now expected to live for over 20 years, allowing further investigation into the QOL of these patients due to the high percentage of patients living in the aftermath of breast cancer, (Cancer Research UK, 2014b). Participants will also include breast cancer patients in varying stages of the disease, during chemotherapy and after chemotherapy treatment. This will allow me to discover if the use of reflexology can be beneficial throughout the stages of cancer.

I will be conducting a systematic review of current medical studies, current articles, statistics and government documentations related to reflexology in female breast cancer patients to gain sufficient knowledge. Resources such as the web (in particular medical databases such as PubMed and Medline), library books, newspapers, and NHS documents will be used to collect the research. Once a sufficient amount of documents have been collected I will be documenting and critically analysing all research, highlighting all sections of important information, in particular looking at the effect of reflexology on QOL variables. In addition to this I will be analysing the strength of all documents in order to avoid biased results and opinions, distinguishing between poor quality studies from good quality studies. To do this I will be documenting the type of research documents I have used, the author, where that particular document has come from, who the document is intended for, the date it was published, and its significance to my dissertation topic.

Secondary research methods will be used as opposed to primary research methods due to the numerous ethical issues that would arise if primary research methods were used. The main ethical issue that would occur through conducting my own research would be the lack of scientific evidence to prove that reflexology would be beneficial, and therefore conducting a study without scientific evidence to prove its benefits/dangers would be ethically incorrect. In addition to this, permission from the patient's oncologist/GP/nurses and the patients themselves would be required before conducting the study as well as permission from the University's ethics committee, which would be difficult to gain due to the nature of the topic. The stage of a patient's breast cancer must also be considered with regards to patient's tolerance/fragility. In addition to this confidentiality would prove to be an ethical issue. I therefore concluded that a dissertation in the form of a literature review would be adequate to gain enough knowledge with regards to the chosen topic as well as avoiding the potential ethical issues that would undoubtedly occur.

Through conducting a systematic review of relevant studies and literature I hope to summarise good quality evidence and come to a valid conclusion.

There are a number of potential issues that may occur through writing this dissertation. A main issue that may occur through conducting a literature review would be the inability to neatly document all of my research findings correctly, which is vital in order to include and exclude important findings. To avoid this I will be devising a table to document all research findings, including the date that document was acquired, where the document came from, its significance to my study, author of the document, and who the particular document is intended for.

Another issue that may occur through writing a literature review would be the potential to lose focus from the topic, due to the amount of different possible research areas that could be looked into. To overcome this potential issue I must focus all research into my dissertation topic and always refer to my aims to avoid losing focus.

Chapter 3.

Review of Literature.

The UK incidence rate for female breast cancer is the sixth highest in Europe, and it is estimated that approximately 1 in 8 women will develop breast cancer at some stage in their life. (Cancer Research UK, 2014a). Regardless of this it is now apparent that more than 90% of women diagnosed with breast cancer in the earliest stages will survive the disease for at least five years. (Cancer Research UK, 2014a) These statistics are extremely positive thanks to the numerous treatments now available on the NHS to treat cancer, including Radiotherapy and Chemotherapy.

There have been many studies conducted previously with regards to the effectiveness of reflexology, (MacQueen, 2008), as there is a growing demand for these kinds of complementary therapies (Fouladbakhsh & Stomell, 2007), (See appendix 1). It is apparent however that questions about its effectiveness are still circulating, with some researchers believing that it is simply a placebo effect. According to MacQueen (2008) “When a patient believes that they will get better, specific changes in brain activity can be seen by scanning and other techniques” This is an interesting theory to bear in mind when analysing the results of some of the studies included in this systematic review.

3.1) Chemotherapy Side effects/ Treatments for the relief of cancer-treatment side effects.

Chemotherapy uses cytotoxic drugs to destroy the cancer cells in women who have been diagnosed with breast cancer and can be a very effective treatment. (MacMillan 2012). The treatment is usually recommended for those who have had surgery, to

reduce the risk of the cancer returning. Unfortunately, the Chemotherapy drug not only destroys cancer cells, but also disrupts normal, vital cells which can cause a variety of side effects and severely lower breast cancer patients QOL. (Macmillan 2012). It is believed that fatigue, anaemia, sickness, loss of appetite, risk of infection, and effects on the nerves (pins and needles in hands and feet) are all common side effects of the Chemotherapy drug. (Macmillan 2012). Thankfully, some of these side effects may be eliminated through the prescription of further medication, prescribed by modern day practitioners, oncologists or suggested by nurses. These drugs may include anti sickness tablets, paracetamol or co codamols, and anti-depressants, in the hope to improve the QOL of breast cancer patients. However, although these drugs may alleviate the side effects of the Chemotherapy for a while, and offer short term relief, the side effects related to drugs such as painkillers and anti-depressant's are also numerous, and pose a risk of further lowering QOL in breast cancer patients. The need for complementary therapies such as reflexology for improving QOL in breast cancer patients can be further emphasised upon when considering Laboriola's (2000, p.70) review of the side effects of cancer treatments, in particular Chemotherapy. Laboriola (2000, p.70) mentions six of the most common types of chemotherapeutic agents, all of which have can have extremely unpleasant side effects including absorption difficulties of the agents, gastrointestinal problems and organ stress and toxicity. Worryingly Laboriola (2000, p.69) states that "Hardly a day goes by in my practice where a patient doesn't absolutely refuse chemotherapy" This statement emphasises the severe side effects that Chemotherapy can have on a cancer patient, and therefore ensuring that as many options as possible are available to help a patient improve their QOL is absolutely vital.

Additionally, treatments that are used to relieve cancer-treatment side effects also come with a long list of their very own, QOL lowering side effects. Pain in particular is a major issue for breast cancer sufferers as its origins can stem from such a large number of places and for so many reasons, (BreastCancer.org, 2013). Surgery related pain is possible, along with chemotherapy related pain, radiation therapy - related pain and hormonal therapy-related pain, let alone the pain caused by the cancer itself. (BreastCancer.org, 2013). According to Katz (2002) pain, when not treated has a detrimental effect on all aspects of QOL, with a profound negative impact. In an attempt to diminish pain in these patients, conventional health care practitioners prescribe painkillers such as co-codamols, paracetamols, and anti-inflammatories. These painkillers often produce bothersome side-effects such as constipation, nausea, drowsiness and tiredness, (Whitehall, 2013). Furthermore, Whitehall, (2013) states that “your doctor will usually prescribe a laxative for constipations” as well as “your doctor will usually prescribe anti-sickness medicine for nausea”, and therefore creating a vicious cycle of prescriptions and side-effects that significantly reduce QOL. Indeed it is believed that reflexology may be just as effective as pain killers with Samuel & Ebenezer (2013) discovering that reflexology could increase pain threshold and tolerance, and therefore suggesting that reflexology may be just as useful on its own, without a copious amount of prescriptions.

It is for this reason, that introducing Complementary Therapies such as reflexology to breast cancer patients may be effective in reducing the side effects of chemotherapy, as well as the side effects of other prescribed medications, in order to improve QOL.

3.2) What is QOL?

It is important to clearly understand the true meaning of QOL, before analysing any studies related to it, in order to avoid coming to any incorrect conclusions. The WHO defines QOL as:

“An individual’s perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns” (Skevington, Lotfy, & O’Connell, 2004)

It is apparent that measuring disease alone in patients is insufficient to determine the health status of individuals, particularly in patients with long terms diseases, where a cure is not possible. In the case of breast cancer patients therefore, whose overall health outcome is uncertain, QOL and measuring QOL is vital, in order for changes and improvements to be made, such as introducing other methods, other than conventional health care treatments, to improve QOL, (Skevington, Lotfy, & O’Connell, 2004). It is also important to remember that defining QOL can be challenging, as different groups and different individuals define their QOL differently, depending on their views, mood and psychological state. (CDC, 2011). It is for these reasons that QOL measuring tools have been devised, to measure the multiple domains which define QOL in order to determine the burden of diseases, injuries and disabilities (CDC,2011) .

3.3 – Why Reflexology? The CAM Healthcare Model.

To further understand and gain knowledge as to why some breast cancer patients may choose complementary therapies such as reflexology, to improve their QOL, their behaviour and reasoning’s can be applied to the CAM HealthCare model. The CAM HealthCare Model is as modification of the Behavioural Model of Health, and identifies factors that influence the use of CAM services such as reflexology. It is understood that the CAM HealthCare Model includes indicators that may pull an individual towards complementary therapies, or indeed “push” individuals towards their use. In the case of reflexology for breast cancer patients, personal factors such

as self-efficacy, risk taking, self-care ability and particularly the need for self-control may promote the use of reflexology for improved QOL in these individuals. (See appendix 1). (Fouladbakhsh & Stomell, 2007).

3.4) What is Reflexology? – The theories of Reflexology.

According to Jones & Leslie (2012), “Reflexology is a complex intervention, based on the idea that specific areas on the soles of the feet, correspond to individual internal organs” It is believed that reflexology works upon the theories derived from two healthcare professionals known as Eunice Ingham and Dr William Fitzgerald., (Jones & Leslie (2012). Fitzgerald hypothesised that directed, constant pressure on specific external areas of the human body could cure various forms of illnesses or disease in the body. This hypothesis became known as the “Zone Theory”. Fitzgerald offered a number of theories in an attempt to explain how his hypothesis worked, such as “blocked shock” or “nerve block” as one possible explanation He also hypothesised on the theory of lymphatic relaxation and flow stimulation and that “pathological conditions disappeared as a result”. (Jones & Leslie, (2012).

The Ingham theory is based on personal belief and the remodelling of Fitzgerald’s “Zone Theory”. Eunice Ingham developed the reflexology that is used today, and mapped specific reflex points on the feet, corresponding to each individual organ in the human body. Ingham also believed that diseases and ill-health materialise as crystal like deposits in the feet, and believed that she could diagnose an illness in a patient depending on these crystal deposits. This is known as the “Crystalline Theory”. (Jones & Leslie, n/d).

In addition to these theories, a psychological theory to explain the effects of reflexology also exists. According to Hefferton & Boniwell (2011,p.179) the benefits

of reflexology can be explained through the interpersonal connection or influence of the practitioner, or person who is giving the reflexology, and thus the use of touch can mimic the proposed benefits of reflexology, including physical and psychological benefits, the suggestion can therefore be made that reflexology is a placebo, and its effects depend greatly on the beliefs of those who are receiving it. (Hefferton & Boniwell (2011, p.179)

3.5) Studies.

Claims that reflexology can be beneficial for health are numerous, with aims to increase relaxation, improve circulation, boost energy, cleanse toxins, and reduce stress, (PennyBrohn Cancer Care, 2014). This systematic review aims to discover if the use of reflexology for symptom relief in breast cancer patients can improve their QOL, and also support the opinion that more studies need to be conducted in this area.

A study carried out by Wyatt et al (2012) evaluates the safety of reflexology for patients with advanced stage breast cancer in women. This study is a fairly recent RCT and is therefore relevant for inclusion. A sample of approximately 385 Caucasian women with advanced stage breast cancer participated in the study. The study was a longitudinal, randomised clinical study, set across thirteen oncology clinics in the United States. Women were randomized into three primary groups of reflexology, lay foot manipulation and conventional care. Results of the study revealed significant improvements in physical functioning for the reflexology group of women as opposed to those in the control group. In addition to this severity of dyspnea (breathlessness) (Bass, 1990), was reduced in those patients who received reflexology, again a positive outcome. Findings of this particular study may indicate

and support the opinion that reflexology may be added to existing supportive care to improve QOL in breast cancer patients with advanced stage breast cancer, (Wyatt et al, 2012). Results of the study are reliable due to the fact that it is a longitudinal study with a large sample of participants (n=385) to compare results. In addition to this the study was single blinded with Wyatt et al (2012) stating that:

“Both type of providers (reflexology/lay foot) were instructed in a standard set of interpersonal skills that facilitated appropriate interaction with women while minimizing unnecessary social support and dialogue”

This further adds to the validity of the study due to the fact that those giving the treatment were unable to communicate unnecessarily with the patients and therefore reduce the risk of putting across biased opinion's which may skew the results of the study. Further background research into this study discovered that it was a study funded by the National Institute of Health (NIH), offering a grant of \$3.1 million to study the effects of reflexology on breast cancer patients. Brower (2013) claims that the grant has established safety, feasibility and efficacy for reflexology. Although the results of the study are positive, there is a possibility that the grant may have had a biased effect on the results of the study and therefore encouraging and promoting the positive aspects of reflexology more readily; this must be taken into consideration when analysing the biases of the study.

Another study by Wilkinson et al (2008) conducted a systematic review of five RCT's with inclusion criteria of adult participants with the diagnosis of cancer. It must be noted that this study does not look at breast cancer patients specifically, and this should be taken into consideration when analysing the study. Main aims and objectives for this study included: discovering the effects of reflexology in reducing

pain, nausea, fatigue and constipation, weather reflexology reduced psychological symptoms such as anxiety, and weather reflexology improved QOL. The systematic review discovered that reflexology may provide benefits to patients with cancer as opposed to those patients who received foot massage or no intervention at all.

Despite this it was also noted in Wilkinson's study (2008) that patients did receive considerable benefits from non-specific foot massage. This may indicate that the use of touch alone is beneficial for those suffering from cancer to provide patients with a sense of calm and relaxation, and thus improving QOL, (Therapy Directory, 2015).

However it must be noted that this study was a systematic review and the author's own bias and interpretation of the results should be considered here. The study by Hodgson (2000) in Wilkinson et al (2008) in particular discovered that patients who received reflexology reaped benefits compared to those who were offered foot massage or no intervention at all. Despite this, it was a short term RCT with short-term follow up, therefore the long term effects of reflexology could not be measured on these patients, and may therefore be unreliable, (Wilkinson et al, 2008). Another study in Wilkinson et al, (2008) conducted by Smith and Humphreys (2005) discovered that genuine reflexology was more beneficial than non-specific foot massage on the Profile Of Mood States assessment, (POMS), and also on the Pearson-Byars (Fatigue Feeling Checklist) (Glaus, 1998).

These are important factors when measuring the QOL in breast cancer patients and any improvements in these factors should be considered as beneficial.

Sharp et al (2010) conducted an RCT to discover and evaluate the effects of reflexology on QOL in women with early stage breast-cancer, as opposed to advanced breast-cancer. A fairly recent study, 138 women were randomised, 6 weeks post-breast surgery into self-initiated support group (SIS), SIS plus reflexology, or

SIS plus scalp massage (control for physical and social contact). This particular study used the outcome measures Trial Outcome Index (TOI) of the functional assessment for cancer therapy at primary end point 18 weeks post-breast surgery, and used the Hospital Anxiety and Depression Scale (HADS) and the Mood Rating Scale (MRS) to measure outcomes at 24 weeks post-surgery. Sharp et al (2010) discovered that at the primary end point (18 weeks post breast-surgery) massage, but not reflexology was better than SIS on the TOI, and that both reflexology and massage were better than SIS for MRS relaxation. Interestingly at second end point (24 weeks post breast-surgery) it was discovered that reflexology, not massage, was better than SIS and for relaxation. This may imply that the effects of receiving reflexology may be more beneficial over a longer period of time and therefore suggest that reflexology is clinically worthwhile for improving QOL. Results of this study may further highlight the fact that, in order for reliable results to be discovered, trials and studies need to be long term. Despite this, this study can again be viewed as reliable due to the fact that it is an RCT and therefore decreases the chance of biased results. The study is also set across a period of 24 weeks after breast cancer surgery enabling for the long term benefits of reflexology to be measured. However it must be noted that at 24 weeks post breast – surgery, breast cancer patients may be feeling significantly better regardless of treatment due to the fact that a longer period of time has gone by since surgery. (Sharp et al, 2010).

It was also discovered by Stephenson et al (2007) that partner-delivered reflexology could also result in a decrease in pain intensity and anxiety in cancer patients in general, if correctly taught. Once again it must be noted when analysing this study, that cancer patients in general participated in this study and not breast cancer patients specifically, and therefore may not fully apply to this particular systematic review, it

is however helpful non the less. This particular study included 42 experimental and 44 control subjects compromising of 86 dyads of patients with cancer and their partners. The intervention included a 15-30 minute teaching session of reflexology for the partners, given by a certified reflexologist, with an optional 15-30 minute reflexology session for the partner, and a 30 minute partner delivered reflexology session for the patient. The control group received a 30 minute reading session from their partner. Pain was measured using two different tools; these were the Brief Pain Inventory (BPI) and the Short-Form McGill Pain Questionnaire (SF-MPQ). The BPI allows the patients to indicate how the pain affects their daily activities as well as indicating the location of pain. In addition to this the sensation of pain e.g. (burning, throbbing, and stabbing) was measured using the SF-MPQ. It was discovered that, following the initial partner delivered foot reflexology, patients experienced a significant difference in pain symptoms and anxiety (Stephenson et al, 2007). Implications of this study could be particularly useful in hospitals or communities with lack of time, facilities, or finance to offer reflexology for breast cancer patients, as hospitals could simply offer reflexology training sessions to those partners who are interested, and therefore giving the opportunity to improve QOL of a breast cancer patient from home. The results of this study could also relate to the results of Wilkinson (2008), and the concept that the use of touch alone, and not just the exact technique of reflexology, could improve QOL in breast cancer patients. In addition to this, data for the study was collected over a 21 month period, and therefore enabling for a substantial amount of data to be collected in this time, which could further strengthen the reliability of the study. Despite this, it was noted in the study that there was a chance that the results could be biased, due to the fact that the

individual training the partners' reflexology were also responsible for administering the questionnaires.

An additional study discovered that following a foot reflexology intervention on both feet for 30 minutes significantly decreased anxiety in patients with lung or breast cancer. (Stephenson, Weinrich, Tavakoli, 2000). The study included approximately 23 female inpatients over the age of 65 on an income of \$20,000 a year or more. This quasi-experimental study also discovered that patients with breast cancer specifically experienced a significant decrease in pain after the intervention. The results of this study again appear to be positive and are particularly useful in promoting the benefits of reflexology for cancer patients. Results of this study further emphasise the fact that reflexology may be introduced into a health care setting in an attempt to decrease the side effects of cancer treatments and improve QOL in these patients. However reliability of this study is much weaker than of those previously mentioned for a number of reasons. This particular study only focuses on one healthcare setting in the United States, therefore restricting the ability to gain a larger amount of participants. The small sample of participants (n=23) in particular tarnishes the validity and usefulness of the study for this kind of research. The design of the study may also have particular impact on its strength due to being a quasi-experimental design. Although a quasi-experimental study is relevant to evaluate benefits of a particular intervention, scientific literature appears to focus on ways to improve and further develop the quasi-experimental design, suggesting that it possesses a number of weaknesses, (Harris et al, 2006).

Chapter 4.

Methodology.

4.1) Design/Rationale.

A systematic review of secondary research was conducted of current medical studies and journal articles, those of which did not include grey literature. The decision was made to use secondary research methods to avoid the numerous ethical issues that would undoubtedly occur if primary research methods were to be used. As previously mentioned in Labriola (2000, p.2), modern healthcare providers in Western countries are unfamiliar with Complementary Therapies such as Reflexology, and tend to avoid signposting towards this type of treatment, due to the fact that their benefits still remain scientifically unproven. Conducting primary research on this topic would therefore be ethically incorrect as well as dangerous. In addition to this gathering permission from Oncologists/GP's and Nurses to conduct primary research would be difficult, again due to the lack of scientific evidence suggesting the benefits of reflexology and it's safety. As well as this, the nature of the disease and its health implications would also have to be taken into consideration with primary research. Cancer Research UK (2015) states that reflexology should not be used or may not be suitable for those with "circulatory problems, inflammation or blood clots in the leg veins, gout, foot ulcers, fungal conditions of the feet, thyroid problems, epilepsy, and a low platelet count". Given that some of these conditions may accompany cancer and develop as a side-effect of chemotherapy, conducting reflexology on patients suffering from these conditions may have health implications, and would again be ethically incorrect. It is for these reasons I believe a systematic review of secondary research would be more appropriate.

4.2) Participants/Inclusion Criteria.

Participants and inclusion criteria for utilisation in the systematic review of literature included:

- RCT's, Quasi- experimental, and Systematic Reviews including RCT's.
- Adult's with a diagnosis of breast cancer, in early stage/advanced stage.
- Receiving treatment in a healthcare setting.
- Reflexology carried out by a qualified reflexologist/partner giving reflexology.
- QOL factors measured using validated tools (e.g. POMS, HADS, MRS).

4.3) Inclusion criteria for Study Design – Rationale.

The decision was made to include RCT's in the literature review due to the reliability of this kind of study. According to PHAST and the Department of Health (2011), RCT's are considered the most rigorous method of determining whether a cause-effect relationship exists between an intervention and an outcome". The strengths of an RCT are numerous, they provide the best kind of epidemiological study from which to draw a conclusion and enables blinding, therefore reducing the risk of bias conclusions, (PHAST & Department of Health, 2011). Despite this, there are flaws to be found in RCT's as with any other type of study such as being expensive and time consuming and it is important that these are noted, (PHAST & Department of Health, 2011). Quasi-experimental studies are particularly beneficial to evaluate the benefits of particular interventions and were included in the systematic review for this reason (Harris et al, 2006). According to Harris et al (2006) there is a growing use and need of quasi-experimental studies in the medical field and within other medical disciplines, and should therefore prove to be beneficial for this particular

systematic review. Despite this it is important to recognize the numerous flaws within this type of study. It is believed that a lack of random assignment is a major weakness of a quasi –experimental study, which can lead to doubt about whether or not an outcome occurred due to an intervention or an alternative explanation, (Harris et al 2006). It is important to consider these particular flaws when critically analysing a study, especially if the study is poorly designed to avoid reaching an invalid, incorrect conclusion.

4.4) Inclusion Criteria For Participants – Rationale.

Including participants at both the early stages of breast cancer and advanced stages of cancer allows for investigation and debate as to whether or not reflexology can have a different effect on QOL, depending on which stage of the disease a patient is at, which is again valuable in debating whether or not reflexology would be useful in a healthcare setting to improve QOL in breast cancer patients.

4.5) Inclusion Criteria for Validated QOL measuring tools.

Including studies in the systematic review that use validated QOL measuring tools is very important for the reliability of the study. QOL measuring tools are particularly important for patients suffering from a chronic illness when a cure is not possible, such as breast cancer, as a way of determining the impact of health care (Burckhard & Anderson, 2003). Some of the QOL tools used in the studies included in this systematic review were:

The Profile of Mood State (POMS) : By McNair, Lorr and Droppleman (1971), POMS provides a method of assessing active mood states through 65-self report items using the 5-point Likert scale. (StatisticsSolutions, 2014)

The Brief Pain Inventory (BPI): By Charles & Cleeland (1991). “The BPI allows patients to rate their severity of pain and the degree to which their pain interferes with common dimensions of feeling and function” (Cleeland, 2009)

Functional Assessment of Cancer Therapy – Breast (FACT-B): A 44-item self-report instrument designed to measure multidimensional QOL in patients with breast cancer, (Brady et al, 2007).

4.6) Procedure.

Web databases and online journal databases were used to gather studies including the NCBI (PubMed), Cancer Nursing Journals, and the Cochrane Library. The search terms “Reflexology, Breast Cancer, and QOL” were used to search for relevant studies. These particular databases were used due to their relevance and reliability to the topic. All three databases provide access to biomedical and genomic information, specifically for those with an interest in gaining high-quality information to improve healthcare knowledge, including doctors and nurses and should therefore produce reliable studies. No language restrictions were used to ensure that a large selection of studies were available, (Cochrane, 2015).

Those studies that fell short of the inclusion criteria were disregarded, including studies that had no relevance to reflexology specifically, studies that did not measure QOL outcomes, studies that were not available in the English language, and those studies including patients without diagnoses of cancer.

Full text articles were then sought after for all studies that met the inclusion criteria. These studies were then documented into a table with all relevant information including,

- Title, Author, Year, and Database
- Design
- Condition
- Intervention/Method
- Primary Outcome measured

(See Table 1, Appendices 1).

4.7) The Holland & Rees Critiquing Framework.

In order to critically analyse the included studies correctly and to exclude a bias opinion, the Holland & Rees critiquing Framework (2010) was used and applied accordingly. The Holland & Rees framework (2010) was developed and published specifically for nursing student's, offering a guide to research and evidence based practice to enable students to utilise research and evidence based practice in assignment work. For my dissertation, the guidelines for critiquing quantitative research articles was used, due to the fact that chosen studies were RCT's or included the results of RCT studies. The framework included a table of twelve different aspects to consider whilst analysing research articles including, focus of study, background, aims of study, methodology or broad approach, tool of data collection, method of data analysis, sample, ethical considerations, main findings, conclusion and recommendations, overall strengths and limitations and application to practice. The twelve aspects of the framework were used accordingly and proved helpful in utilising and critically analysing various studies. The Holland & Rees critiquing Framework (2010) was used due to its relevance to the topic area of my dissertation. Although the framework is specifically aimed at nursing students its

aspects are relevant to the medical studies included in my dissertation, whose origins lie in medical databases. It was therefore concluded that this particular framework would be appropriate and useful to achieve a non-biased analysis of various studies. (See appendix 2.)

4.8) The Jadad Scale (1996).

The Jada scale is a procedure which can be used to assess the methodological qualities of clinical trials. It consists of a 3-item, five-point quality scale (Jadad et al, 1996). This particular assessment tool was used to evaluate the methodological quality of the three RCT's included in the systematic review in order to determine their reliability and strength. According to Hempel et al (2011)" the Jadad Scale is one of the few tools where the psychometric properties have been evaluated and are seen as acceptable," and therefore appropriate for use in this dissertation. However, Hempel et al (2011) also highlight some of the flaws associated with the Jadad Scale. It is believed that the double blinding criterion accounts for only a very small amount of studies and that many trials involve devices which make double blinding impractical or impossible. In addition to this Berger (2006) in The Journal of Rheumatology (2006) states that "it must be acknowledged that the Jadad Scale is not a perfect instrument" due to the fact that places great emphasises on the quality of reporting as opposed to actual methodological quality of a trial. Regardless of this however, the Jadad Scale is simple and is the "only instrument that has been conducted according to psychometric principles" (Berger, 2006). It is also important to remember that these statements by Berger (2006) are his personal opinions and interpretations of the scale, and are not supported by any existing evidence. (Journal of Rheumatology, 2006)

(See Appendix 3.)

Ethical Approval.

No ethical approval was required for this dissertation due to the nature of the study design.

Chapter 5.

Results.

A total of 203 studies were found between the three online databases using the search terms “Reflexology, Breast Cancer and QOL”. PubMed had the largest amount of research available with a total of 174 potential studies, however only four of these studies were relevant to inclusion criteria. One of these studies was disregarded due to poor methodological assessment and not meeting the requirements of the Holland and Rees critiquing framework leaving three studies for inclusion. Cancer Nursing’s online journal database revealed a total of 16 studies with one meeting the inclusion criteria. Thirteen studies were found in the Cochrane Library database with three meeting the inclusion criteria, however only one of these studies were used due to cross referencing with other online databases (PubMed).

Figures, 1, 2, and 3 provide a brief summary of the search results.

Fig.1.

<u>Database: Pub Med.</u>
Search terms: “Reflexology, breast cancer, and QOL”
No of studies retrieved: (n= 174)
No of studies not meeting inclusion criteria (n= 170)
No of studies excluded due to language restrictions: (n=1)
Total No. of studies used: (n=3)

Fig.2.

<u>Database: Cancer Nursing Online Journals.</u>
Search terms: “Reflexology, breast cancer, and QOL”
No. of studies retrieved: (n=16)
No. of studies not meeting inclusion criteria: (n=15)
No of studies excluded due to language restrictions: (n=0)
Total No. of studies used: (n=1)

Fig.3.

<u>Database: Cochrane Library.</u>
Search terms: “Reflexology, breast cancer, and QOL”
No. of studies retrieved: (n=13)
No. of studies not meeting inclusion criteria: (n=10)
No. of studies excluded due to language restrictions: (n=0)
Total No. of studies used: (n=1).

A total of 5 RCT's, systematic reviews, and quasi-experimental studies met the inclusion criteria and were utilized in the systematic review. Table 1 shows a brief summary of these studies.

Table 1 – A Brief Summary of included studies.

Title/Author/Year	Design	Condition	Intervention/Method	Primary Outcome measured (QOL/Pain ect)
A Randomised Controlled trial of the Psychological effects of Reflexology in Early Brest Cancer. (Sharp, 2010) PubMed	Randomised Controlled Trial (RCT)	Early stage breast cancer (post-op)	Self-initiated support (SIS), SIS and Reflexology, SIS and scalp massage.	Trial Outcome Index tool, Hospital anxiety and depression scale (HADS) and Mood rate scale (MRS)
Health Related Quality of Life Outcomes: A Reflexology Trial with patients with Advanced – stage breast cancer (Wyatt et al, 2012) PubMed	RCT	Advanced stage Breast cancer patients under-going Chemotherapy.	Reflexology and Lay foot Manipulation.	Breast Cancer related QOL and Physical Functioning.
Reflexology for symptom relief in patients with Cancer. (Wilkinson et al, 2008) Cancer Nursing.	Systematic Review	Patients with Cancer in general.	Electronic databases to identify relevant RCTs	Physical symptoms, Psychological symptoms and QOL.
Partner – delivered reflexology: Effects on cancer pain and anxiety (Stephenson et al, 2007) Cochrane Library.	Experimental pre-test/post-test's RCTs.	Patients with metastatic cancer including lung ,breast, colorectal, hand and neck cancer and lymphedema	Partner – delivered Reflexology.	Pain intensity and Anxiety.
The Effects of Foot Reflexology on patients with breast and lung cancer (Stephenson, Weinrich, Tavakoli, 2000) PubMed/Cochrane Library.	Quasi-experimental, pre/post, crossover.	Patients with breast or lung cancer	Intervention condition of foot reflexology	Anxiety and Pain.

The 3 RCT's were measured for methodological quality against the Jadad Scale (1996), studies conducted by Wilkinson et al (2008) and Stephenson, Weinrich, and Tavakoli (2000) were excluded from this process as they were Systematic Reviews and quasi-experimental studies. Table 1.2 shows the result of the 3 RCT studies.

Table 2- Methodological quality assessment of RCT's.

Jadad Scale (1996).	Sharp (2010)	Wyatt et al (2012)	Stephenson et al (2007)
Is the Study Randomised?	Yes (+1)	Yes (+1)	Yes (+1) -(0) for no description of randomization process
Is the randomisation process appropriate and reported in the study?	Yes (+1)	Yes (+1)	No (-0)
Is the Study double blinded?	No (0)	No (0) Only interviewers were blinded to group assignment.	No (-0)
Is the double blinding method appropriate and reported in the study?	No (0)	No (0)	No (-0)
Are the reasons for patient withdrawals and dropouts described, for each treatment group?	No (0) Dropout reasons were given, but not specifically for each treatment group.	Yes (+1)	Yes (+1)
Overall Quality assessment score.	2	3	1

According to the assessment given using the Jadad Scale 1996, it appears that the study conducted by Wyatt et al (2012) is the most reliable and therefore the most valuable RCT for this dissertation.

The following states the findings of each individual study, along with the characteristics and methodological quality results of the studies.

Study 1 - Wyatt et al (2012)

Wyatt et al (2012) included a total of 385 participants in their study. All participants were female, with a diagnosis of advanced stage breast cancer. No age restrictions were mentioned in the study. Women were randomized into three primary groups, reflexology (n=95), LFM (n=95), and conventional care (n=96). In the reflexology group 3 women dropped out, along with 5 in the LFM group. It was noted that 89% of women in the reflexology group completed all 4 sessions, and 90% of women in the LFM group completed all 4 sessions.

Effects of intervention on outcome.

“Significant differences among study groups (reflexology, LFM, and conventional care) were limited to physical function, dyspnea, and fatigue. Unfortunately no differences were found on breast cancer-specific QOL variables, depressive symptomatology, anxiety, pain, and nausea.”

“Dyspnea: Women in the reflexology group reported significant reductions in mean dyspnea severity compared to the control group and the LFM group.”

“Physical functioning: A mean improvement was found for physical functioning for the reflexology group compared to control group.”

“Fatigue: Participants who received LFM reported significantly lower fatigue scores than those in the control group.”

(Wyatt et al, 2012)

Study Quality.

A score of 3 on the Jadad Scale (1996) was given to this RCT conducted by Wyatt et al (2012) for methodological quality.

Study 2 - Sharp (2010).

A total of 183 participants were included in this study. Participants included adult women with early stage breast cancer, Participants were randomized at 6 weeks post-surgery to self-initiated support (SIS), SIS plus reflexology, or SIS plus scalp

massage, reflexology and massage compromised eight sessions at weekly intervals. At primary end point (18 weeks) post-surgery the primary outcome measure was the trial outcome index (TOI) of the functional assessment of cancer (FACT-B). Secondary outcome measures were the hospital anxiety and depression scale (HADS) and the mood rating scale (MRS) at secondary end point (24 weeks) post-surgery. Participant's main reasons for dropping out or exclusion from the study included being unable to complete the study questionnaires, and being unwilling to give written informed consent.

Effects of Intervention on Outcome.

"It was discovered that at primary end point, massage but not reflexology was significantly better than SIS on the TOI. Reflexology and massage were both better than SIS for MRS relaxation."

"Massage was better than reflexology and SIS for MRS easygoingness."

"At second end point, reflexology was better than SIS and massage on TOI and MRS easygoingness."

"No significant difference between reflexology or massage".

"No significant difference between group differences in HADS anxiety and depression."

(Sharp, 2010)

Study Quality.

A score of 2 can be given to the study according to the Jadad Scale (1996).

Study 3- Stephenson et al (2007).

A total of 86 patients and their partners participated in this study. The experimental group consisted of 42 participants, with 44 participants in the control group. Participants included females (n=51%) and males, with a mean age of 58.3 years, and 66% had a high school education or less. It was noted that 58% were Caucasian, 40% were African American and 1% Filipino. In this study 16 different types of

cancer were represented, 23% of patients had lung cancer, followed by breast, colorectal, head and neck cancer, and lymphoma. Pain and anxiety were the main research variables. Study was carried out across four hospital settings. Three patients in experimental group were too ill to receive the intervention. Participant in the control group was able to take part in the reading but not answer the pre intervention visual analogue scale

Effects of Intervention on Outcome.

“Patients reported significant decrease in pain intensity and anxiety. These decreases were immediate.”

“Minimal changes were seen in the control group”

(Stephenson et al, 2007)

Study Quality.

A score of 1 can be given to the study according to the Jadad Scale (1996).

Study 4 - Wilkinson 2008.

A total of 387 studies were retrieved, however only 5 of the studies were used and met inclusion criteria. Within these studies 10 patients preferred not to participate, were unable to participate or were ineligible (Hodgson, 2000), 21 participants withdrew due to not being able to complete all required questionnaires (Smith + Humphris, 2005), 7 participants passed away, 1 participant was unable to attend the treatment, and 1 participant had no baseline measures recorded (Ross et al , 2002). In Stephenson et al (2000), 20% of the patients who were invited to participate declined with no reason. Participants included adult participants with a diagnosis of cancer receiving care in any health care setting.

Effects of Intervention on Outcome.

No firm conclusions can be drawn about the effectiveness of reflexology for the relief of cancer treatment symptoms. Despite this evidence does suggest that

reflexology may confer benefits to those with cancer over those offered foot massage or no-intervention control. However it was also stated that

“The study of Ross et al found that palliative care patients seemed to benefit more from the sham reflexology than from genuine reflexology”

(Wilkinson, 2008)

Study Quality.

The checklist's developed by Juni et al and Jadad et al were used to assess quality of the studies included.

Study 5 - Stephenson, Weinrich, Tavakoli, (2000).

A total of 23, Caucasian women aged 65 or over were included in this study. These women had 12 or fewer years of education and received an annual income of \$20,000 or more. All participants had a diagnosis of either breast or lung cancer and were receiving regular opioids and adjuvant medications on the day of intervention. Research variables were anxiety and pain.

Effects of Intervention on Outcome.

“Patients with both lung and breast cancer experienced a significant decrease in anxiety.”

“Patients with breast cancer reported a significant decrease in pain.”

(Stephenson, Weinrich, Tavakoli, 2000).

Study Quality.

No mention given in study with regards to assessing quality of study. In addition to this no information was given as to how participants were gathered and no information given with regards to measuring the outcome variables.

Chapter 6

Discussion

6.1) Summary of main findings.

Currently, there are numerous claims that suggest the use of reflexology may be beneficial for breast cancer patients in improving QOL and reducing the side effects of cancer treatments. Kunz (2003, p.33) strongly believes that the use of reflexology in cancer hospices can “improve a patients QOL, offer practical ways to cope with life threatening illness, provide comfort and enhance both the patient’s and carer’s sense of physical, emotional and spiritual wellbeing”. The results that are presented in each study are positive. Seemingly, reflexology provided significantly decreased severity in dyspnea, an increase in physical functioning, a positive outcome on the TOI and MRS, and a significant decrease in pain and anxiety. Despite this however it appears that there is simply not enough scientific evidence available to validate these claims. The qualities of the 5 studies reviewed in this dissertation were not plausible enough to come to a valid conclusion with regards to the effectiveness of reflexology in improving QOL in breast cancer patients; they do however support the fact that more valid, scientific research needs to be conducted in this area. In addition to this none of the studies that were analysed measured any side effects of the reflexology intervention, therefore allowing for speculation to arise with regards to the safety of reflexology. Furthermore only two out of the five included studies mentioned the use of a specific reflexology technique. Bearing in mind that some studies produced the results that “sham” reflexology or “LFM” provided positive QOL benefits for cancer patients, this may raise questions about the actual need for specific reflexology, as opposed to just massage, or touch alone.

6.2) Main Findings: Strengths and Weaknesses.

Stephenson, Weinrich, Tavakoli (2000) included only a small sample of participants (n=23),and offered only a 30 minute reflexology session. This may lead to problems in correctly interpreting the results of the study and may not be considered as reliable, (Hackshaw, 2008). In addition to this, participants were only recruited from one oncology health care setting, and therefore limiting recruitment numbers, this may have been done to enable easier access to ethical approval. As well as this, the

study did not mention if and how the side effects of reflexology were measured. Furthermore Stephenson, Weinrich & Tavakoli included participants with a diagnosis of breast cancer and lung cancer, therefore results of this study cannot be specifically applied to promoting the use of reflexology for breast cancer patients only. Furthermore, despite reporting that participants experienced a significant decrease in anxiety and pain, there was no mention of a follow-up intervention to further validate these results. The design of the study can also raise questions with regards to its validity. As previously mentioned it is apparent that many biases can occur in a quasi-experimental study, and lack of randomization can prove to be a major weakness, (Harris et al, 2006), this, along with the small number of participants involved in this study could seriously affect the seemingly positive outcomes that were reported. Despite these negative aspects of the study, results did conclude to be positive, with patients with breast and lung cancer reporting a significant decrease in anxiety, and breast cancer patients in particular experiencing a decrease in pain severity. (See Study 5, p.35), (Stephenson, Weinrich,Tavakoli, 2000).

The study of Wilkinson (2008) reflects the findings, strengths and weaknesses of this particular systematic review. Although the search conducted by Wilkinson (2008) retrieved a substantial 387 studies, only five of these were relevant and met inclusion criteria, again highlighting the issue that more scientifically correct research needs to be conducted on reflexology and breast cancer patients specifically. In addition to this, Wilkinson (2008) highlights weaknesses in the studies that were relevant, similar to those that occurred in the studies included in this systematic review. The studies of Hodgson (2000) and Stephenson et al (2000) were small trials with short-term follow-up, with a larger study conducted by Smith and Humphris (2005) reporting very little difference between the sham reflexology and the real reflexology. Wilkinson (2008) reported that “the paucity of the data in the 5 trials means that no firm conclusion can be drawn about the effectiveness of the intervention”. Despite this, results of the study may suggest that reflexology may offer benefits for patients suffering with cancer, whilst providing a strong rationale for the need to conduct more scientific research into the topic. In addition to this, the study may raise questions with regards to the benefit of touch alone, and not specifically reflexology. Studies included in Wilkinson (2008) seem to suggest that

some patients benefited more from non-specific foot massage than from the reflexology itself, with Wilkinson (2008) stating that “The study of Ross et al found that palliative care patients seemed to benefit more from the sham reflexology than from genuine reflexology” (See Study 4 – p. 34), suggesting that the actual correct technique of reflexology is not an important factor in reaping benefits for improving QOL,(TherapyDierectory,2015).

The suggestion that non-specific massage could be more beneficial than reflexology itself can be further researched when considering the results of all 5 studies included in this particular systematic review. It appears that only two of the five studies that were analysed in the systematic review mentioned a specific reflexology technique. The study by Stephenson et al (2007) delivered a reflexology intervention using the original “Ingham” method. This particular method focuses on relaxing and balancing the body’s system, whilst working on all of the reflexes, applying pressure accordingly, depending on the patient’s pain tolerance (ntpages, 2015). Stephenson et al (2007) discovered that patients who received this reflexology intervention experienced decrease in pain severity and anxiety, (see Study 3-p.34), which suggests that the Ingham method of reflexology may provide positive effects. Despite this it must be noted that the study by Stephenson et al (2007) measured partner-delivered reflexology, and therefore questions may arise as to whether or not the Ingham method was carried out correctly, further questioning the actual significance of specific reflexology techniques and the validity of the study.

A reliable study was conducted by Wyatt et al (2012) with positive results reported. “Significant reductions in dyspnea severity” after reflexology were reported in this study, along with an “improvement in physical functioning, and significantly lower fatigue scores after receiving LFM.” (See Study 1, p.32), (Wyatt et al, 2012). In addition to this, a large sample of participants was included in the study and a methodological quality assessment score of 3 was obtained according to the Jada Scale (1996), therefore strengthening the validity of the study. Furthermore Wyatt et al (2012) also described the reflexology protocol that was used in the study, with a nine-step protocol put in place. It was cited in Bower (2013) that this nine-step protocol would “open the pathways to receive chemotherapy more thoroughly” and “release the residual by-products of the chemo after it has accomplished its function” This nine-step protocol provided an understanding of the reflexology techniques that

can be used as well as providing insight into how benefits can be acquired through this technique. (See appendix 4). Questions may arise with regards to the validity of this study after background research revealed that the study derived from a grant, offered by the National Institute of Health (NIH) to study the effects of reflexology in breast cancer patients (Bower, 2013). This could be seen as a negative when reviewing the biases in a study, as it could be possible that the grant money may have skewed the results of this study in some way, to promote the use of reflexology in cancer patients.

The results of the study conducted by Sharp et al (2010) are again in favour of the use of reflexology to improve QOL in breast cancer patients during the early stages. An RCT study with a large sample of participants, the results reported in Sharp et al (2010) are reliable. Furthermore, Sharp et al (2010) included a number of reliable QOL measuring tools in this study, including the FACT-B and the MRS which proved particularly useful in measuring specific QOL outcomes. In addition to this the study suggests that the effects of reflexology as an intervention may be more beneficial over a longer period of time, as initially (18 weeks post breast surgery) massage was better than SIS on the TOI, however at 24 weeks post breast surgery, reflexology was better than SIS for relaxation. (See study 2, p.33), (Sharp, 2010).

6.3) Review methods: Strengths and Weaknesses.

There are many strengths and weaknesses that must be noted from this systematic review before coming to a valid conclusion. Although an attempt was made to retrieve as many high quality studies as possible, lack of research regarding reflexology, breast cancer and QOL meant that this was not possible. In addition to this an attempt should have been made to use different search terms and a wider variety of databases to avoid potentially missing out on vital studies. It also became apparent that language proved to be a barrier when retrieving certain studies and therefore potential high quality studies had to be disregarded. As previously mentioned, regrettably only a small number of papers were eligible for inclusion in the systematic review, and therefore a strong, valid conclusion cannot possibly be made when relying on such a small sample of studies, regardless of their outcomes and quality. Despite this, the systematic review offers clear, transparent data and an attempt to highlight the biases that may occur in certain studies involved in this area

of research, as well as discovering the clear need for more scientifically correct research to be conducted

6.4) Relevance to current available literature.

As previously mentioned results of this systematic review are similar to those found in Wilkinson (2008), with both systematic reviews experiencing the same issues such as lack of research meeting inclusion criteria and studies including biases. The findings of this systematic review also echo those findings in Wilkinson et al (2008), in that patients could benefit just as much, if not more, from sham reflexology than from reflexology itself. Results of this systematic review also support the opinion of Labriola (2000, p.2), who believes that conventional health care providers, including doctors and nurses rarely signpost towards complementary therapies such as reflexology due to the lack of scientific evidence that exists to promote its safety and benefits in improving QOL. However, Labriola (2000, p.68) also states that

“Not scientifically studied doesn’t mean that these treatments don’t work, but rather that no one has tested them scientifically. Some conventional treatments, for example, are the result of practical experience with individual patients rather than with a scientific study.”

This statement may raise the opinion that complementary therapies such as reflexology should be promoted, and allowed to be explored freely under the guidance of a GP/Oncologist alongside a trained reflexologist. It may also suggest that conventional health care provider have no reason to not sign post towards reflexology. This statement is particularly supported by the results of each study in this systematic review, with positive results found in all five studies throughout, but lack of scientifically correct procedures and biases acting as a hindrance on their validity.

Results of this study also mirror the opinion of Cancer Research UK (2015) to some extent, who states that “there is no scientific evidence available to support the use of reflexology as a treatment of cancer.” Although this statement is true, results of this systematic review show that there is evidence available to support the use of reflexology, alongside conventional treatments to improve QOL in breast cancer patients, but not to be used as a treatment alone. In addition to this Cancer Research

UK (2015) state the benefits of reflexology for breast cancer patients, and these benefits are supported by the findings in the five studies included in this systematic review. These benefits include uplifting mood and thus giving a feeling of well-being, helping to relieve pain, and to relax and cope with stress and anxiety (Cancer Research UK, 2015). Results of this systematic review also support a similar statement by Kunz (2003, p.26) that reflexology can “help a patient relax, cope with stress, relieve pain, and improve general well-being”.

Furthermore, results of this systematic review support the statement made by Kunz (2003, p.26) in that reflexology offers “a natural, drug free treatment option” as well as reducing pain and promoting general relaxation. As previously mentioned pain plays a significant role in reducing QOL, (Katz, 2002), particularly when a patient is going through a disease that causes so much pain, for different reasons and from different origins. Wyatt et al (2012) in particular supports the suggestion that reflexology can help to promote relaxation in breast cancer patients as her study discovered that the severity of dyspnea was reduced after the reflexology intervention, compared to the control group and the lay foot manipulation group. PennyBrohn Cancer Care (2014) highlights benefits of reflexology, including increased relaxation, more energy, a reduction in stress and improved circulation. The results of Sharp (2010), coincide with these benefits, with reflexology and massage both proving to be better than SIS on the MRS for relaxation and reflexology appearing to be better than SIS and massage on TOI and MRS easygoingness. PennyBrohn Cancer Care’s (2014) statement is also echoed in the results of Stephenson 2007, and Stephenson, Weinrich, & Tavakoli (2000), with both studies reporting significant decrease in anxiety after the reflexology intervention, which would in turn increase relaxation.

Interestingly the psychological theory mentioned by Hefferon & Boniwell (2011) of reflexology is also appropriate to the results found in the systematic review. It was discovered in one study retrieved by Wilkinson (2008) that some palliative care patients seemed to benefit more from the sham reflexology than the genuine reflexology (See Study 4, p. 34) . In addition to this the results produced by Stephenson et al (2007) may further support the psychological theory of reflexology due to the fact that the reflexology intervention of the “Ingham” method was delivered by the patient’s partners. Stephenson et al (2007) stated that only a “15-30”

minute teaching session on reflexology was given to the partner, this may undoubtedly raise the question as to whether or not this was a sufficient amount of time for the partner to correctly learn the “Ingham” technique of reflexology and apply it accordingly. If not, then the study conducted by Stephenson et al (2007) certainly supports the psychological theory of reflexology, in that touch can mimic the exact benefits of reflexology. (Hefferon & Boniwell, 2011).

It is therefore apparent that there are plenty of beliefs and opinions among Cancer charities and Complementary therapy providers, that reflexology can produce positive effects, particularly for QOL variables. These beliefs and opinions are strongly supported by the scientific evidence that is available in this area of research, with results of these studies coinciding with the statements that are made. It is important to remember however, that only a small sample of scientific evidence does exist, and that these small samples are not nearly enough to fully supports the statements that are being made with regards to reflexology and QOL.

6.5) Implications for current practice and future research.

Implications for future research.

The results reported in this systematic review dissertation may be used to highlight the need for a substantial amount of correct scientific research to be conducted in the area of reflexology for breast cancer patients. In addition to this, the systematic review may be used to imply that methodological improvements need to be made to those studies which already exist in order to further strengthen the quality and validity of these studies. In doing this the benefits of reflexology, which clearly exist, will have a valid place in the conventional health care setting, whilst allowing those patients who are going through the physical and psychological distress of breast cancer, a non-invasive treatment method to improve their QOL.

Implications for current practice.

As well as implications for future research, results of this systematic review may be used in favour of the use of reflexology for improving QOL in breast cancer patients, through improving patient’s knowledge and options. Medical oncologist’s and GP’s may also consider the outcomes of this systematic review and begin to promote the use of reflexology for QOL of life purposes as opposed to conventional medications

such as Paracetamol and anti-depressants. This Systematic Review may prove to be particularly useful for those patients going through breast cancer themselves and their family members, who may be looking for an alternative method of improving their QOL. Important questions were also highlighted in this Systematic Review, which could also lead to significant implications for current practice, such as whether or not the specific technique of reflexology is significant in improving QOL or whether it is the use of touch alone and non-specific foot massage that provided these benefits and positive results on QOL outcomes. Such questions may have serious implications on reflexology interventions which already exist, particularly when evaluating the cost of trained reflexologists for employment on the NHS.

Chapter 7.

Conclusion.

This dissertation set out to determine whether or not the use of reflexology really can improve QOL in breast cancer patients, during and after conventional cancer treatment, as well as raise awareness with regards to the effectiveness of reflexology, and highlight the pros and cons of making reflexology readily available on the NHS for breast cancer patients.

Results of this systematic review are not plausible enough to come to a strong valid conclusion and state that the use of reflexology for symptom relief in breast cancer patients can improve their QOL. The quality of the five studies included in this systematic review, along with the lack of scientific evidence available to meet inclusion criteria means that it is not possible to ethically promote the use of reflexology to improve QOL in breast cancer patients. In addition to this no studies could be retrieved from the searches carried out that looked into the effects of reflexology on breast cancer patients after conventional cancer treatment, and therefore failing to reach one of the main aims set out in this dissertation.

Furthermore it has not been possible to prove or highlight the pros and cons of making reflexology readily available on the NHS, once again due to the lack of valid evidence that is available, in favour of reflexology. Despite this, results of this systematic review can be taken and suggested as an option for breast cancer patients, for them to explore the pros and cons of reflexology at their own will. An obvious benefit of introducing reflexology as a complementary therapy for breast cancer patients, to improve QOL on the NHS for example, is that breast cancer patients could be able to avoid the unpleasant side-effects of prescription drugs such as painkillers (opioids) anti-sickness tablets and anti-depressant tablets to some extent, if they choose. Reducing the intake of these drugs may also provide a feeling of self-control for these patients as well as an increased chance of completing their chemotherapy treatments through an improved QOL. This “feeling of self-control” is mentioned in the CAM Healthcare model as a factor that may influence an individual to participate in CAM therapies such as reflexology, and thus potentially effect the utilization of conventional health care treatments. (Fouladbakhsh & Stommel, 2007). (See appendix 1.)

This systematic review has managed to raise awareness with regards to the effectiveness of reflexology for breast cancer patients, with results of each of the studies included in this dissertation proving to be in favour of reflexology, and highlighting its effectiveness in improving QOL variables. Furthermore, the use of all “grey literature” included in this dissertation builds towards a positive picture for the use of reflexology in breast cancer patients. Despite this, once again lack of valid evidence means that a firm positive conclusion cannot possibly be made, and therefore more research needs to be conducted into this topic.

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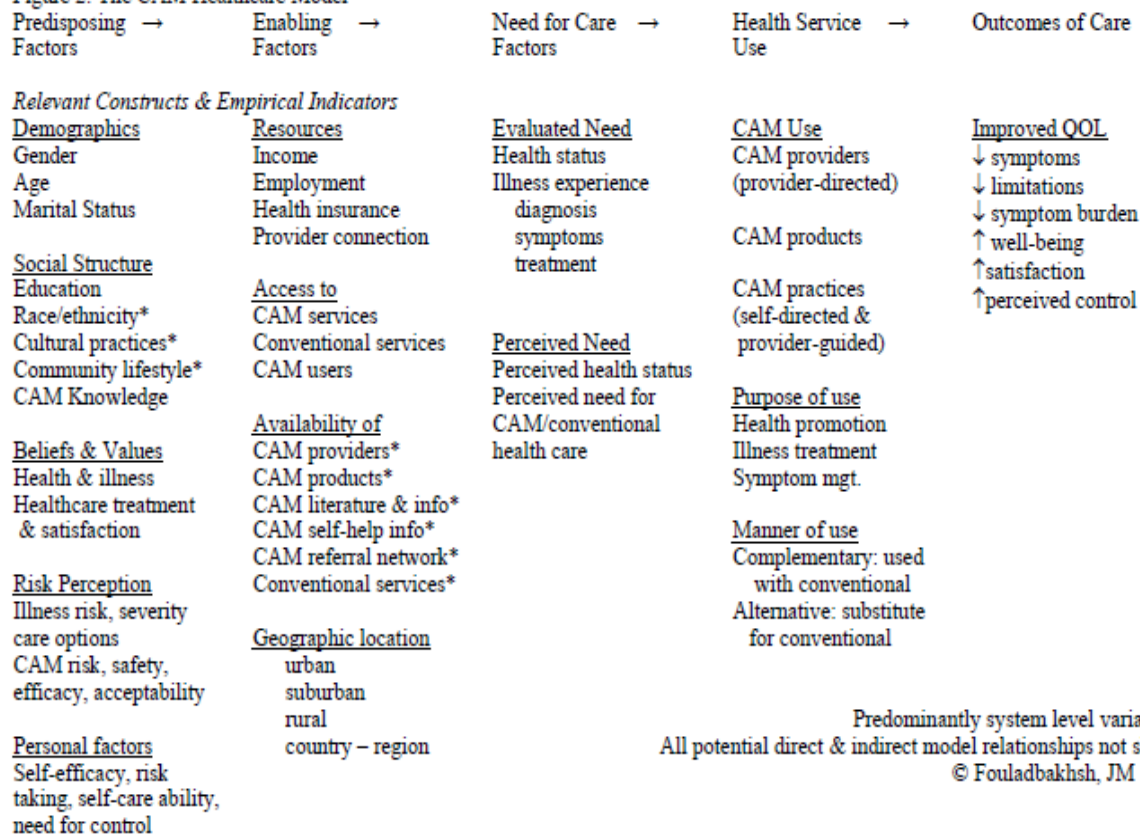
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Appendices

1)

Figure 2: The CAM Healthcare Model



2).

A framework for critiquing quantitative research articles

Below is Table 7.2, the critiquing framework you will see in chapter 7 in the book. This is best used with quantitative research articles. You might like to print this off to keep with you when you critique quantitative articles.

Aspect	Questions
Focus	What topic is the concern of this article? Can you identify measurable 'variables' in the title or researcher's statement concerning their main interest? Is this an important topic for research?
Background	How does the researcher argue that the topic is worthwhile? How widespread or big a problem is it? Is the seriousness of the topic reinforced by the previous studies? Is there a thorough review of the literature outlining current knowledge on this topic? Are the key variables defined and an attempt made to consider how they can be measured? E.g. definitions of 'pain' or 'anxiety' and descriptions of scales frequently used to measure them.
Aim	What is the statement of the aim of the data collection? This usually begins with the word 'to', e.g. 'The aim of this study is 'to examine/determine/establish/compare/etc.'. If it is a randomised control trial there may be a hypothesis.
Methodology or Broad approach	Within a quantitative approach, is it a survey, experimental (RCT), or correlation study? Does seem suitable given the aim of the study?
Tool of data collection	What was the method used to collect the data? Had this been used in previous studies and so may be regarded as reliable or accurate? If not, was it piloted? Is there any mention of reliability or validity? Is there a rationale given for the choice of tool? Could an alternative tool have been considered?
Method of data analysis and presentation	Is the method of processing and analysing the results described in the methods section, such as statistical process through SPSS computer analysis, and are the results clearly presented in the results/findings section? Does the researcher clearly explain any statistical techniques or methods of presentation such as tables, graphs, pie charts?
Sample	On how many people, events, or things are the results based? If questionnaires were used, what was the response rate? If it was a randomised control trial, what was the dropout rate? Is either of these likely to have an impact on the results? Were there inclusion and exclusion criteria stated? Were these reasonable given the research question and the nature of the sample? Do they limit to whom the results may apply? What method was used to select who were included in the study (the sampling strategy)? Does the sample suffer from any kind of bias?
Ethical considerations	Did an ethics committee (LREC, or in US an Institutional Review Board 'IRB') approve the study? Was informed consent gained and mention made of confidentiality? Could the study be said to be ethically rigorous?
Main Findings	What did they find in answer to their aim? What were the large results that relate to the aim of the study?
Conclusion and Recommendations	Did they give a clear answer to their aim? If they stated a hypothesis, did they say if this was supported or rejected? Were clear recommendations made (who should do what, how, now)?
Overall strengths and limitations	What would you say were the aspects of the study they did well? What aspects were less successful? Did they acknowledge any limitations to the study?
Application to practice	How do the results relate to practice? Should any changes be considered?

3).

- 1. Was the study described as randomized (this includes words such as randomly, random, and randomization)?**
Yes=1, No=0
- 2. Was the method used to generate the sequence of randomization described and appropriate (table of random numbers, computer-generated, etc)?**
Yes=1, No=0
- 3. Was the study described as double blind?**
Yes=1, No=0
- 4. Was the method of double blinding described and appropriate (identical placebo, active placebo, dummy, etc)?**
Yes=1, No=0
- 5. Was there a description of withdrawals and dropouts?**
Yes=1, No=0
- 6. Deduct one point if the method used to generate the sequence of randomization was described and it was inappropriate (e.g. patients were allocated alternately, or according to date of birth, hospital number, etc).**
Described but inappropriate = -1, Described and appropriate = 0
- 7. Deduct one point if the study was described as double blind but the method of blinding was inappropriate (e.g. comparison of tablet vs. injection with no double dummy).**
Described but inappropriate = -1, Described and appropriate = 0