

An integrative literature review of the utilisation of reflexology in adults with chronic disease

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ABBREVIATIONS

ADA	American Dietetic Association
CASP	Critical Appraisal Skills Programme
CLBP	Chronic Low Back Pain
IBS	Irritable Bowel Syndrome
MMD	Mosby's Medical Dictionary
NEUD	New English Usage Dictionary
OWD	Oxford Wordpower Dictionary

ABSTRACT

This is an integrative literature review of the utilisation of reflexology as complementary and alternative treatment modality in adults with chronic disease. Anecdotal evidence has claimed potential health benefits of reflexology for patients with various chronic diseases. In this study, selected databases that were accessible were searched using keywords such as reflexology therapy, zone therapy and combinations thereof. Databases such as SA Nexus, SAePublications, ProQuest, Web of Knowledge, EBSCOhost Platform, ScienceDirect, Cochrane Library and Google Advanced Scholar were searched for primary studies and reviews of primary studies from 2000 until the end of 2008 (N = 1171). Primary experimental and non-experimental studies in any language with an abstract in English were identified. Only studies that complied with the inclusion criteria were reviewed and appraised (n = 35) for study quality with appropriate tools from the Critical Appraisal Skills Programme (CASP) and the American Dietetic Association's (ADA) Evidence analysis manual. Evidence extraction, analysis and synthesis were done to review available evidence by means of the evidence class rating and evidence grading of strength prescribed in the ADA's manual. Study findings represent a statistical significant reduction in the frequency of seizures of patients with intractable epilepsy, an improvement of sensory and urinary symptoms associated with multiple sclerosis and a clinical significant reduction of pain and anxiety in patients with cancer and fibromyalgia syndrome to increase overall well-being and quality of life. No statistical significant evidence was reported on benefits of reflexology for irritable bowel syndrome, menopausal symptoms, chronic low back pain and asthma. Thus there appears to be fair evidence of the effectiveness of reflexology, in addition clinical evidence supports the utilisation of reflexology to promote well-being and quality of life in adults with chronic disease.

KEYWORDS:

Reflexology; integrative literature review; chronic disease.

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CHAPTER 1

1. INTRODUCTION AND OVERVIEW

The focus of this study is the utilisation of reflexology in adults with chronic disease. The intention of this study is to critically appraise and synthesise research published in this field to contribute to the scientific knowledge base of nursing by formulating conclusions based on synthesised evidence from primary studies. In the high-tech world of health care, a number of complementary and alternative medicine (CAM) modalities use principles of energy transformation and manipulation to enhance vitality and well-being in individuals. Reflexology is such a CAM modality that is used in the United Kingdom (UK) and the United States of America (USA) by professional nurses, known as integrative nurse practitioners (Amster, Cogert, Lie & Scherger, 2000:80; Libster, 2001:121; Mackereth, Dryden & Frankel, 2000:70). Chapter 1 provides an overview of the study, first by presenting the background and rationale for the study, followed by the problem statement, the purpose and the researcher's paradigmatic perspective. An outline of the research design and research method concludes Chapter 1.

1.1 BACKGROUND TO THE STUDY

In the practice of comprehensive nursing care, nurses are often confronted with requests from patients regarding information on, accessibility to and provisioning of CAM modalities, such as reflexology, acupuncture and therapeutic touch. Patients request advice on CAM modalities and highly value the opinion of a trusted nurse in this regard; they expect nurses to be able to react informatively on these inquiries. However, it still appears to be an unfamiliar territory to nurses.

1.1.1 Complementary and alternative medicine

Complementary and alternative medicine is a term that covers a broad range of over a hundred philosophies, approaches, therapeutic modalities and healing

practices that conventional medicine does not commonly study, understand, use or make available to patients (Koithan, 2009:18). These therapies are used in combination with conventional medicine and are then referred to as 'complementary'; if these therapies are used on their own they are referred to as 'alternative'. CAM modalities are provided by a divergent group of professional and lay caregivers, with different educational backgrounds and professional credentials.

CAM has become increasingly popular over the last decade in the USA, the UK and Australia (Lee, Charn, Chew & Ng, 2004:655; Mackereth *et al.*, 2000:66). The use of CAM has always been very common among Chinese and other Asian patients in countries such as Singapore, Hong Kong and Taiwan and is influenced by these countries' psychosocial philosophies, value systems and cultural beliefs (Lee *et al.*, 2004:656). Even in South Africa, the use of CAM is becoming more popular, as revealed by a cross-sectional survey conducted in 2005 in Pretoria among HIV-infected patients (Malangu, 2007:273).

It is a commonly held belief that patients often use CAM when they are dissatisfied with conventional medicine, when it is too costly, impersonal, has too many side effects or seems to be ineffective; however, it has been stated by Lee *et al.* (2004:656) that CAM offers patients an alternative model that is more appropriate and comfortable to fit their personal value system and cultural beliefs. Patients use CAM during chronic disease to cope with the various symptoms and as a self-care management tool. They do not reject conventional care as such, but use CAM complementary to conventional care (Thorne, Paterson, Russel & Schultz, 2002:671). Reflexology is one of the CAM modalities that are frequently used in this way (Mackereth *et al.*, 2000:66).

In the high-tech world of health care, a number of CAM modalities, such as reflexology, use principles of energy transformation and manipulation to enhance vitality and well-being in individuals. Energy manipulation and stimulation are concepts that configure strongly along with relaxation as a possible explanation for the overall effects of reflexology on vitality and well-being in patients (Carpenter & Neal, 2005:115). According to conventional principles, reflexology effects may be attributed to the *gate control theory*, an accepted mechanism to explain pain control on which analgesia such as transcutaneous electrical nerve stimulation

(TENS) is thought to work. Another commonly held belief is that reflexology may work by stimulating the release of endorphins and encephalins – the natural pain relievers and mood enhancers of the human body. These two theories are more in keeping with the Western approach to health care, because they are demonstrable and conceivable. Reflexology authorities disagree with these explanations and appear to advocate more controversial theories such as the energy flow theory and the meridian theory (Mackereth & Tiran, 2002:11).

The energy flow theory suggests that positive and negative energy receptors in the feet connect with energy receptors in the ground. It therefore supports the spatial relationship of the feet with the earth. Oedema or poor circulation in the feet leads to impairment of the ability of the feet to pick up energy from the earth, so the flow of energy is blocked. Reflexology opens these blockages by direct stimulation of reflex points on the feet and allows the feet to regain their links with the energy receptors in the ground. However, this theory fails to explain adequately why hand, ear and face reflexology is also effective (Mackereth & Tiran, 2002:11).

The most popular theory among reflexologists appears to be the meridian theory, which is based on principles of traditional Chinese medicine (Crane, 1997:5; Dougans, 2005:36; Mackereth & Tiran, 2002:12). The meridian theory suggests that vital energy, called “chi”, flows in channels, called meridians, throughout the human body from top to toe and vice versa. These meridians often follow the line of a neural pathway or blood vessel. If the body, mind and spirit are in equilibrium, the energy flows freely, but disease, pain or stress results in energy changes that lead to imbalances in energy and stagnancies thereof. Reflexology is one means of rebalancing the “chi” by unblocking, stimulating or sedating the energy flow through direct stimulation of the reflex points on the feet, ear or hands (Crane, 1997:50; Dougans, 2005:36; Mackereth & Tiran, 2002:11).

Dougans (2005:20), an authority on reflexology, is of the opinion that reflexology offers a large scope of benefits to individuals that suffer from chronic diseases. She explains that chronic diseases are the result of energy blockages, stagnancies and imbalances in the meridians of the human body (Dougans, 2005:11–13). These energy imbalances and stagnancies deprive the human body of vitality and well-being and are most often the forerunners of more serious organ and system disorders. Reflexology stimulates the corresponding reflex points on

the soles of the feet in order “to indirectly clear the energy stagnancies and blockages along the meridians” to enhance vitality and well-being in the organs of the human body (Dougans, 2005:12).

1.1.2 Chronic disease

Smeltzer, Bare, Hinkle and Cheever (2008:166) define chronic disease as chronic conditions that have a prolonged course of at least three months that do not resolve spontaneously and for which complete cures are rare. Chronic diseases such as cardiovascular diseases, diabetes mellitus, stroke, Aids and tuberculosis are relatively common in South Africa (Connor, Rheeder, Bryer, Meredith, Beukes, Dubb & Fritz, 2005:334). In South Africa there appears to be an increase in chronic diseases, especially in relation to the high incidence of HIV in sub-Saharan Africa (Bryer, 2008:151; Connor *et al.*, 2005:334; Modi, Modi & Mochan, 2006:1247). Chronic infectious diseases, such as HIV/AIDS and tuberculosis, which are paralleled by the increasing threat of non-communicable chronic diseases, place a heavy burden on chronic health care provisioning in South Africa.

Chronic disease can result from a secondary complication of acute illness, genetic factors, injury or unhealthy lifestyle behaviours. The management of chronic diseases includes:

- coming to terms with personal identity;
- lifestyle changes to prevent further complications;
- alleviation of symptoms; and
- adaptation to the overall physical impairments and disabilities of the painstaking chronic disease.

In South Africa, sedentary life style, smoking, obesity and alcohol abuse are of the most important lifestyle-related risk factors for chronic diseases such as diabetes mellitus, hypertension and cardiovascular disease (Bryer, 2008:151–152; Groenewald, Vos, Norman, Laubscher, Van Walbeek, Sabojee, Sitas & Bradshaw, 2007:674). Chronic kidney disease shares common risk factors, such as smoking, hypertension, diabetes, obesity and hyperlipidaemia, with cardiovascular disease and stroke (Connor *et al.*, 2005:335; Katz, Mdleleni, Shezi, Butler & Gerntholtz,

2007:360). Tuberculosis, cardiovascular disease and stroke place a tremendous burden on health care systems, especially in combination with the HIV/AIDS epidemic (Connor, Neurol, Thorogood, Casserly, Dobson & Warlow, 2004:627; Norman, Bradshaw, Schneider, Pieterse & Groenewald, 2006:12). Figure 1.1 clearly illustrates the revised leading specific causes of death in South Africa, as estimated by the South African Medical Research Council in 2000.

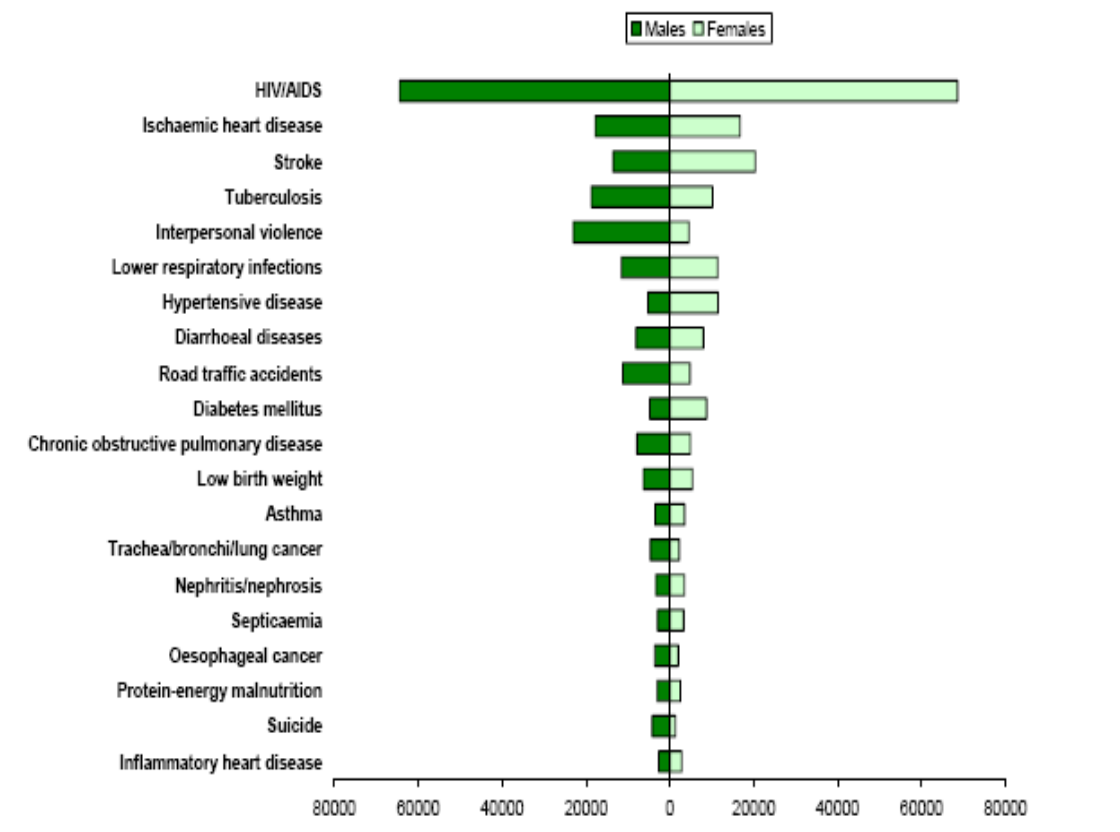


Figure 1.1: Revised leading specific causes of death, South Africa 2000
(Norman et al., 2006:12)

Chronic disease firstly interferes with the activities of daily living and secondly with the overall quality of life of the individual. Individuals that suffer from ruthless chronic disease may become totally or partially dependent on caregivers to perform the routine activities of daily living, due to poor vitality and impaired well-being. The symptoms of chronic disease can be alleviated by conventional medicine and comprehensive health care, but place a high burden on health care provisioning. Furthermore, chronic deterioration often occurs, which places considerable stress on the individual's energy, vitality and well-being (Smeltzer et al., 2008:167).

1.2 PROBLEM STATEMENT

The prevalence of chronic disease in South Africa is high, as seen in Figure 1.1. Chronic disease places a high burden on comprehensive health care provisioning and health care resources (Bryer, 2008:151; Connor *et al.*, 2005:334; Modi *et al.*, 2006:1247; Tollman *et al.*, 2008:897). Chronic disease furthermore appears to be a silent threat to the individual's quality of life, as demonstrated by low physical vitality, impaired well-being and physical/cognitive deficits (Smeltzer *et al.*, 2008:167).

Management of chronic disease includes coming to terms with personal identity, making of various life style changes, alleviating disease specific symptoms and adaptation to cognitive impairments and physical disabilities. Patients with chronic disease are mostly managed by themselves, community nurses, specialised tertiary units, tertiary multi- professional teams and private physicians in the community. This creates exhaustion on personal, private and governmental budgets (Connor, Neurol, Thorogood, Casserly, Dobson & Warlow, 2004:627; Norman, Bradshaw, Schneider, Pieterse & Groenewald, 2006:12). Patients with chronic disease therefore explore other alternative and innovative treatments to complement tertiary care. CAM has become increasingly popular over the last decade in the USA, the UK and Australia (Lee, Charn, Chew & Ng, 2004:655; Libster, 2001:121; Mackereth *et al.*, 2000:66). Even in South Africa, the use of CAM is becoming more popular, as revealed by a cross-sectional survey conducted in 2005 in Pretoria among HIV-infected patients (Malangu, 2007:273).

It is a commonly held belief that patients often use CAM when they are dissatisfied with conventional medicine, when it is too costly, impersonal, has too many side effects or seems to be ineffective (Libster, 2001:8-12; Mackereth *et al.*, 2000:61). However, it has been stated by Lee *et al.* (2004:656), that CAM offers patients an alternative model that is more appropriate and comfortable to fit their personal value system and cultural beliefs. Patients use CAM during chronic disease to cope with the various symptoms as a self-care management tool. They do not reject conventional care as such, but use CAM complementary to conventional care (Thorne, Paterson, Russel & Schultz, 2002:671). Reflexology is one of the CAM modalities that are frequently used in this way (Mackereth *et al.*, 2000:66).

Reflexology, such a CAM modality that is used by patients suffering from chronic disease is not well known amongst professional health care workers in South Africa and therefore should be evaluated and investigated by scientific research. Reflexology claims to address the energy reserves of the human body to promote vitality and well-being by balancing the energy imbalances in the human body (Dougans, 2005:12). Mackereth *et al.* (2000:67) state that there is a growing number of people accessing reflexology in a variety of health care and private settings, and that health professionals should therefore consider expanding and developing their practice by undertaking research on this matter in order to gain evidence-based knowledge to make informed decisions regarding access to and provisioning of reflexology as CAM modality to patients during comprehensive health care. The theory of the underlying action and mechanism of reflexology is still open for debate due to the paucity of formal research data on this matter.

A number of research studies indicate consensus on an overall view of the benefit of reflexology to vitality and well-being in individuals by improvements in poor blood circulation, fatigue, constipation, anxiety, loss of appetite and poor coping mechanisms (Brown & Lido, 2008:130; Gunnarsdottir, 2007:219–223; Hiroyuki, Takako, Yoko, Hiroshi, Hiroyasu & Tatsuya, 2004:795; Walsh & Wilson, 1999:35). Reflexology may also contribute to community health care by empowering the patients and caregivers to manage chronic disease symptoms interactively under nursing supervision. Studies conducted on pain relief, pain control and anxiety in patients suffering from cancer and dementia showed a positive outcome when reflexology therapy was offered to these patients in this regard (Hodgson & Andersen, 2008:269; Stephenson, Weinrich & Tavakoli, 2007:127).

The utilisation of reflexology in chronic disease should therefore be reviewed, as there appears to be an increasing interest in complementing conventional care with reflexology during chronic disease. Studies should include both quantitative and qualitative approaches to evaluate the value of reflexology as a complementary modality to enhance vitality and well-being in adults with chronic disease to promote their overall quality of life.

1.2.1 Research question

The following question was raised:

What evidence exists on the utilisation of reflexology as CAM modality in adults with chronic disease?

1.2.2 Purpose of the study

The purpose of this study was to explore and describe identified scientific evidence of the utilisation of reflexology as CAM modality to promote well-being and quality of life in adults with chronic disease.

1.3 PARADIGMATIC PERSPECTIVE

In nursing practice, research and practice form an important partnership to expand the knowledge base of nursing as a discipline that is based on scientific evidence. Philosophical trends of the present and past, as well as individual meta-paradigms of the role-players in the nursing discipline, determine nursing practice and research (Proctor, 2002:45). Reflexology is a holistic CAM modality with assumptions and principles of traditional Chinese medicine (Dougans, 2005:64–68). In order to structure the specific reality of this study and to guide the researcher's assumptions, the paradigm for this study is described in the following sections.

1.3.1 Meta-theoretical assumptions

Meta-theoretical assumptions are defined by Klopper (2008:67) as statements that are self-evident and not testable.

The researcher holds a Judeo-Christian philosophical perspective. As Christian researcher, the researcher acknowledges God as the Almighty Creator of man, heaven and earth. God is Spirit and Energy that made all things through Him and from Him. As stated in John 1:4–5: "In Him was life and the life was the light of men. The light shines in the darkness and the darkness has not overcome it" (The Holy Bible: English Standard Version, 2005).

The researcher views the creation of heaven and earth as a transformation, manipulation and exchange of Spirit and Energy by God Himself. The researcher believes that God created heaven and earth by the utilisation of His own Spirit and Energy. Energy configures central in the life process, because it exists from conception until death. Energy is transformed and manipulated during the life process in many ways; it is complemented with nutrition, oxygen and various chemical supplements. Energy can be drained by manipulation of physical or psychosocial realities and disease. Physical reality is stipulated by the manifestation of matter that is made up of energy. The life experience, intellectual capacity and cognitive development of human beings determine their psychosocial reality, which is time related.

In Genesis 1:27 it is written: “so God created man in his own image, in the image of God he created him; male and female he created them” (The Holy Bible: English Standard Version, 2005). Man is also made from the earth and given *life* by God’s breath, because we read in Genesis 2:7 “then the Lord God formed the man of dust from the ground and breathed into his nostrils *the breath of life*, and the man become a living creature” (The Holy Bible: English Standard Version, 2005). Man is therefore a privileged image of the Spirit and Energy of God. Life is a physical, psychosocial journey towards wholeness and eternity. In order to pursuit wholeness, man utilises physical, psychosocial, emotional, spiritual and cognitive energy to realise the maturation process of life itself.

1.3.1.1 Person (*alt. man*)

A person is a holistic being, in constant interaction with the external and internal environment to maintain integrity or wholeness. A person’s wholeness on physical, psychosocial and cognitive level is intertwined with his/her spiritual beliefs, cognition, social values and physical energy reserves (Rand Afrikaans University, 1992:7–9).

The researcher views the adult with chronic disease as a human being with a complex unity of body, mind and soul, embedded in society and in constant interaction with his/her internal and external environment in his/her pursuit of wholeness.

1.3.1.2 Environment

The researcher views the environment of the adult with chronic disease as consisting of an internal and external environment in constant interaction with each other.

The internal environment is viewed as a physical, psychosocial and cognitive system within the adult. The internal environment of an adult is shaped by past experience, genetic make-up, specific synchronised physiological responses, spiritual beliefs, sanctity and the freedom of choice to participate independently in the deliberate life processes or not.

The external environment is comprised of the physical, psycho-socio-cultural and economical surroundings that continuously impact with specific advantages, threats and forces on the adult as part of the life process. All the environmental information is recorded by the sensory organs and conceptually constructed by the adult's language, culture, beliefs and cognition.

1.3.1.3 Health/Disease

The researcher views *health* in adults with chronic disease as a state of experiencing the maximal residual potential of wholeness/integrity on physical, social, psychological and mental levels as demonstrated through achieving his/her personal potential and ability in physical vitality, psychosocial well-being and mental/cognitive functioning. The healthy adult with chronic disease has adequate energy, spirit, creativity and cognitive ability to pursue and maintain his/her personal productivity and wholeness/integrity.

The researcher views illness in adults with chronic disease as a state of imbalance in the physical, social, psychological and mental homeostasis of the adult as demonstrated by poor physical vitality, low productivity, psychosocial instability, subjective feelings of un-wellness and impaired cognitive abilities. Therefore the adult with chronic disease experiences substantial losses in his/her physical energy, spirit, creativity and cognitive ability during illness while he/she tries to pursue wholeness/ integrity.

1.3.1.4 Nursing

The researcher views nursing as an art, science, cyclic process and active intervention, with the aim of:

- rendering comprehensive preventative, therapeutic, supportive and tertiary health care;
- healing and empowering the adult when in need, as demonstrated by the loss of homeostasis, physical energy, spirit, creativity and cognitive ability;
- assessing the adult on physical, social, psychological and mental level;
- identifying homeostatic imbalances in the adult's physical, social, psychological and mental levels;
- drawing nursing diagnoses and plan accordingly for identified imbalances;
- implementing the planned nursing interventions; and
- evaluating the implemented nursing interventions, determining progress, achievement of goals and applying remedial nursing interventions where applicable.

The therapeutic relationship between the nurse and the patient is based on confidentiality, unconditional love, careful observation, tolerance, mutual participation, openness, honesty, respect and fairness to each other.

1.3.2 Theoretical assumptions

Traditional Chinese medicine principles directly influence the assumptions of reflexology and the debate on the underlying action of reflexology. Although, as a devoted Christian, the researcher does not subscribe to the religious teachings of traditional Chinese religion, as a Christian scientist the researcher can apply the principles of traditional Chinese medicine and its understanding to reflexology in the comprehensive health care of adults with chronic disease.

Reflexology is a holistic CAM modality that stipulates harmony and balance between the body, mind, soul and physical environment for health, vitality and well-being. Oriental philosophy and cosmology was shaped by Taoism and Confucianism, which held that the cosmos is an eternal whole, uncreated yet

constantly recreating itself (Lett, 2000:5). Vital energy is a universal force that manifests on earth as a balanced energy of life, the so-called chi (Dougans, 2005:18; Lett, 2000:5; Simmons, 2001:33).

Within the human body, vital energy manifests as chemical, electrical and molecular energy that the person receives randomly at conception. It cannot be destroyed or created, but can be transformed and manipulated under specific conditions. Vital energy or “chi” flows freely in the human body in channels called meridians. A meridian follows the neural path or blood vessel that supplies a specific organ with the necessary nerve and blood supply. The meridians are named according to the main organ to which they relate. Meridians are linked and manifest as pairs to complement each other and to bring forth harmony/balance in the human body. In reality, all the meridians are interconnected by internal branches to actually present as one continuous meridian throughout the body and to distribute vital energy to the human body as a whole system, but they are classified and named according to the main body organ to which they supply vital energy so as to be more comprehensible. Specific meridians attend to specific physiological balances and functions in the human body (Dougans, 2005:18; Lett, 2000:5). Main meridians of the human body are displayed diagrammatically in Figure 1.3.

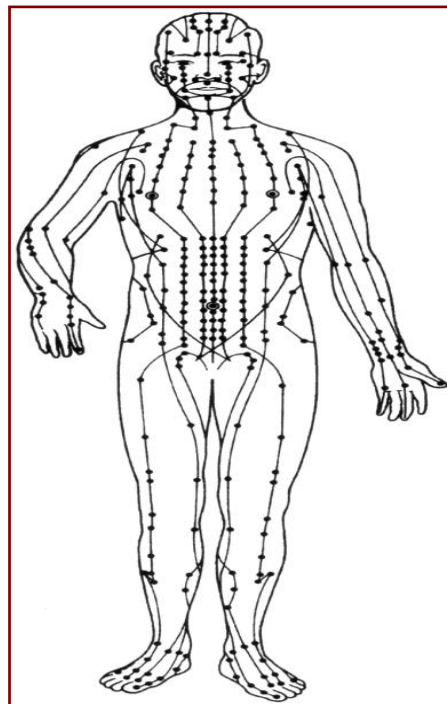


Figure 1.2: Main meridians of the human body (Dougans, 2005:9)

The meridians flow in a zigzag pattern throughout the human body to provide vital energy to all the organs, tissues and cells in the human body. Specific points indicated with a dot on the diagram indicate the superficial flow of the vital energy, and the energy can be stimulated or sedated here with the fingers or acupuncture needles directly on these points to affect the flow of energy. When the procedure is done with the fingers, it is called reflexology, and when acupuncture needles are used, it is called acupuncture (Dougans, 2005:9).

According to Dougans (2005:175), the feet can be seen as a micro-cosmos of the human body, and therefore the organs of the whole body are displayed on the soles of the feet. The particular reflex points of each organ are therefore portrayed on the soles of the feet. Stimulation of the specific reflex points on the feet leads to direct stimulation of the vital energy in the associated organs and meridians. Energy imbalances, stagnations and deficits are as such identified and rebalanced by direct finger stimulation by the therapist on the corresponding reflex points and meridians (Dougans, 2005:179; Stormer, 2004:16). The micro-cosmos of the human body on the feet is displayed diagrammatically in Figure 1.4.

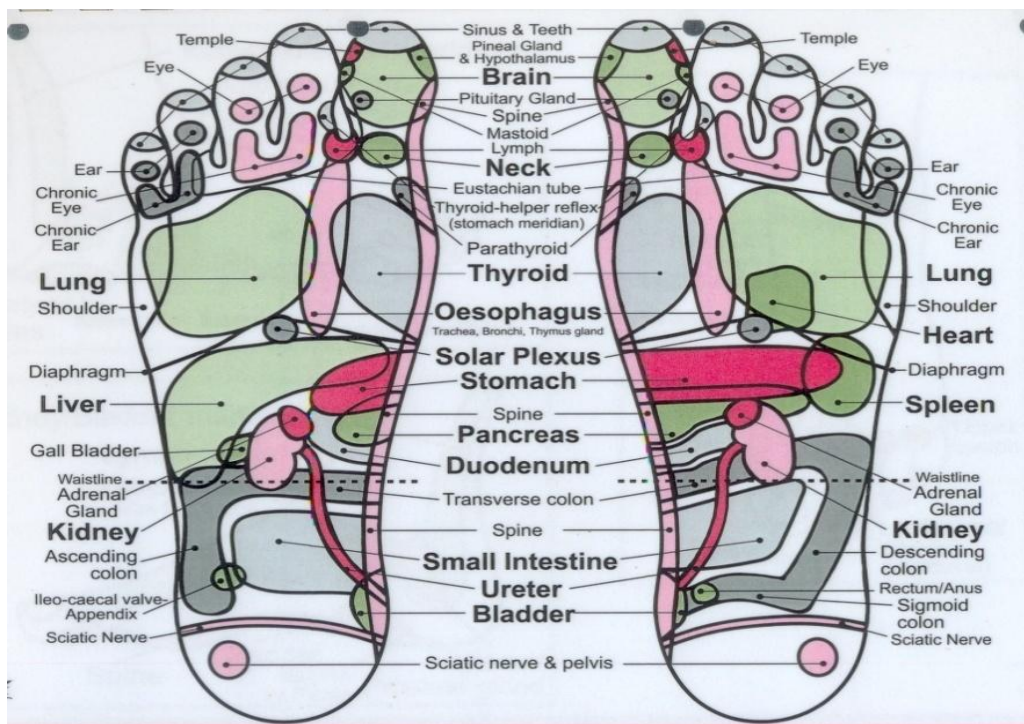


Figure 1.3: Micro-cosmos of the human body displayed on the feet
(Dougans, 2003:1)

Reflexology in this way provides the means whereby the body can be synchronised to balance its vital energy (chi) in the meridians and simultaneously alert the body's own healing potential to heal itself according to traditional Chinese medicine principles.

1.3.3 Theoretical definitions

The theoretical concepts used in this study are displayed in Table 1.1 for more clarity and to guide the process of the integrative literature review.

Table 1.1: Theoretical definitions of the study

Adult	A person that is a grown-up or has reached maturity. One who is over the age stated by the law, usually 18 years (NEUD, 2001:11).
Chronic disease	Medical conditions or health problems with associated symptoms or disabilities that have a prolonged course of at least three months, that do not resolve spontaneously and for which complete cures are rare (Smeltzer <i>et al.</i> , 2008:166).
Reflexology therapy	A CAM modality that consists of a non-invasive therapeutic intervention, performed manually with the hands and fingers of the reflexologist to stimulate precision reflex points/zones on the feet, hands, face, ears or body of the individual to balance the vital energy or life force in the human body so as to promote health, vitality and well-being. Stimulation should be performed according to the principles of Fitzgerald, Ingham, Marquardt, Dougans or Crane. Treatment duration should not be less than 30 minutes and not more than 60 minutes to provide sufficient stimuli to the human body so as to mobilise its own healing powers and prevent over-stimulation of the human body (Dougans, 2005:250–254; Gillanders, 2005:12; Mackereth & Tiran, 2002:5).
Utilisation	To make use of or exploit (OWD, 2006:781).
Abbreviations	<i>Mosby's Medical Dictionary (MMD)</i> <i>New English Usage Dictionary (NEUD)</i> <i>Oxford Wordpower Dictionary (OWD)</i>

1.3.4 Methodological assumptions

The methodological assumptions that will guide this study are in line with Botes' Model of Research (1992:36). Methodological assumptions reflect the researcher's view of the nature and structure of science in nursing research (Botes, 1992:39). These assumptions were set in terms of the aim and methods of research and the

criterion of trustworthiness. The Botes model of nursing research (1992:39) describes research methodology as the research decisions taken within the framework of the so-called determinants of research. These determinants guide the research decisions and facilitate the logic of the macro-argument of the research.

The methodological assumptions of the researcher guided her decisions on the research aim, context and design and gave direction thereof.

The aim of this research was to explore and describe identified scientific evidence of the utilisation of reflexology as CAM modality to promote well-being and quality of life in adults with chronic disease. A contextual approach was used that include both experimental and non-experimental studies that complied with pre-set inclusion criteria.

According to the functional approach in nursing, research should lead to the development of theories in order to improve the practice of nursing (Botes 1991:19). This implies that knowledge gained through this research should be applicable in nursing practice, in the nursing curriculum and nursing research per se. The purpose of this research was therefore explorative and descriptive to contribute to the scientific knowledge base of nursing by formulating conclusions based on synthesized evidence from primary studies to guide evidence based practice of patients with chronic disease.

1.4 RESEARCH DESIGN

The design is descriptive in nature and is aimed at exploring and describing the utilisation of reflexology in adults with chronic disease by means of an integrative literature review.

1.4.1 Method and procedure

The research method selected for this study is an integrative literature review using the procedure of a systematic literature review. Integrative literature reviews critically review identified experimental and non-experimental studies for method and quality, then systematically synthesise the findings of good-quality studies in order to overcome the limitations of the systematic review, which only uses

randomised controlled trials (RCTs) that would not be inclusive enough in a study of this nature as it focus only on effectiveness of the intervention. The integrative literature review allows for the inclusion of experimental and non-experimental research in order to more fully understand the perceptions, experiences, affection and effectiveness of the utilisation of reflexology in adults with chronic disease (Whittemore & Knafl, 2005:546). Therefore, all available evidence of the utilisation of reflexology in adults with chronic disease were critically reviewed to make informed decisions on the access to and provisioning and benefits of reflexology as a CAM modality to such patients. All relevant studies that comply with inclusion criteria were selected, including studies with a qualitative or quantitative approach.

Conventional systematic reviews offer a way of critically appraising the best available evidence and systematising, rationalising and making more explicit the process of review to synthesise certain forms of evidence. The purpose of these reviews is to test theories or to obtain the best available evidence regarding the effectiveness of interventions. The procedure of systematic literature review offers a way of limiting bias during the conduction of an integrative literature review. It furthermore gives more credibility and reliability to the study, because data are collected systematically and pooled from various sound scientific databases. Relevant studies were critically appraised, summarised and synthesised, as is done in systematic reviews (Abalos, Carroli & Mackey, 2005:15–26). The steps to conduct the integrative literature review are displayed in Table 1.2 on the following page.

Table 1.2: Steps of the integrative literature review

1	Formulating the review question. The question is formulated according to the PICOT format. ○ Patient/population of interest ○ Intervention ○ Comparison (if applicable) ○ Outcome ○ Time (if applicable)
2	Generating a search strategy: Identifying keywords for the search. Setting inclusion and exclusion criteria. Deciding on databases. Deciding on inclusion of grey literature. Selecting language. Setting timeframe of studies to be used.
3	Selecting the studies: Initial screening process: Reading the titles and abstracts for relevance. Accurate record keeping of all identified studies and the initial screening process for audit purposes. Manual searching of all the references of identified studies to identify potentially missed studies. Selecting all relevant studies according to selection criteria. Retrieving full-text articles of all relevant studies. Classifying relevant studies by type of research design. Accurate record keeping of included and excluded studies for audit purposes. Creating a sort list of relevant studies included for critical appraisal by indicating author, reference, title, study design, sample, data collection and analysis, quality rating and comments.
4	Performing the critical appraisal: • Completing evidence worksheets. • Assessing methodological quality and validity using appropriate criteria. • Recording assessments on a sheet of quality ratings.
5	Extracting data and drafting a summary of all relevant studies. • The relevant studies are those that comply with the selection criteria and that were found to be of good quality.
6	Critically synthesising the findings.
7	Contextualising the findings. The findings are contextualised to the South African context

The tabulated steps will now be discussed in relation to the proposed study.

1.4.1.1 Step 1: Formulating the review question

The research question for this study is as follows:

What evidence exists on the utilisation of reflexology as CAM modality in adults with chronic disease?

The review question should be a clear identification of the purpose of the review to determine the variables of interest and the sample frame. The review question should address the following components to enhance clarity and rigour:

Patient/population of interest: adults with chronic disease;

Intervention: reflexology;

Comparison: conventional health care (if applicable);

Outcome: to promote well-being and quality of life

Time: duration of treatment (30 to 60 minutes) of the study (Evans, 2001:2; Melnyk & Fineout-Overholt, 2005:30).

Table 1.3: Review question in PICOT format

P	I	C	O	T
Adults with chronic disease	Standardised reflexology therapy (as CAM modality) on precision reflex points/zones according to the principles of Fitzgerald, Ingham, Marquart, Dougans or Crane	Conventional health care	To promote well-being and quality of life	Reflexology treatment 30 to 60 minutes' duration

1.4.1.2 Step 2: Generating a search strategy

A well-defined literature search strategy is critical for the integrative literature review to provide an adequate comprehensive search that ensures accurate results and enhances rigour of the study by limiting publication bias (Whittemore & Knafl, 2005:548).

Databases that are freely available and that cover the fields of CAM, nursing science and conventional medicine as well as published research studies were

selected and searched on the basis of appropriateness and accessibility. A record of the search was kept for audit purposes. Keywords such as reflexology therapy, zone therapy, foot massage and complementary and alternative medicine and combinations thereof, where applicable, were used in the formal search.

Databases that were searched are displayed in Table 1.4.

Table 1.4: Databases used for formal search

DATABASE / PLATFORM	TYPE OF RESEARCH STUDIES	STUDIES IDENTIFIED
SA Nexus (National Research Foundation [NRF])	Completed and current research in South Africa	N = 3
ProQuest	International theses and dissertations	N = 5
<u>EBSCOhost platform:</u> Academic Search Premier Africa-Wide: NiPAD CINAHL Health Source: Nursing/Academic Medline PsycInfo	International journals on health science – primary studies	N = 297
ScienceDirect	International journals on health science – primary studies	N = 415
Web of Knowledge	International journals on health science – primary studies	N = 87
Cochrane Library	International systematic reviews and clinical trials in health science	N = 53
Sabinet online: SAePublications	South African journals and publications – primary studies	N = 1
Google (Advanced Scholar Search)	Medicine Pharmacology and veterinary science	N = 310
<i>Total identified studies</i>		<i>N = 1171</i>

The unit of analysis for the integrative review is primary experimental or non-experimental studies to ensure an in-depth understanding of the phenomenon. The literature search of an integrative literature review should be clearly

documented and inclusion and exclusion criteria should be clearly stated to identify all relevant primary studies (Whittemore & Knafl, 2005:547).

The inclusion and exclusion criteria for this study are displayed in Table 1.5.

Table 1.5: Inclusion and exclusion criteria with rationale for study selection

INCLUSION CRITERIA	EXCLUSION CRITERIA	RATIONALE
Population: - Adults 18 years and older - Male or female with chronic disease	Babies, children and adolescents	To direct review question and focus study population
Setting: - Conventional primary, tertiary and palliative institutional health care settings - Complementary and alternative health care settings - Community	- Hospital intensive care settings - Maternity care settings - Hospital theatre settings	To focus the setting and accommodate any chronic disease
Health status of participants/subjects: Medical diagnosis of any chronic disease. Chronic diseases are medical conditions or health problems with associated symptoms or disabilities that have a prolonged course of at least three months that do not resolve spontaneously and for which complete cures are rare (Smeltzer et al., 2008:166).	- Diagnosis of acute illness - Pregnancy - Healthy individuals	To direct the review question and focus the study population
Study design: - Systematic review - Integrative review - Primary studies of experimental or non-experimental design, including RCTs, non-randomised intervention studies, case studies, cross-sectional studies and case reports - Publications included: Conference abstracts/ Grey literature – international and local theses and dissertations	- Anecdotal evidence - Reflexology books without scientific evidence of utilisation of reflexology therapy in chronic disease - Expert health professional opinions - Consumer articles without scientific evidence of utilisation of reflexology therapy in chronic disease	To identify most appropriate recent research to answer review question
Timeframe: January 2000 to December 2008		To ensure that recent research is included
Language preference: Any language with abstract in English.		A large number of studies on reflexology are done in Eastern countries and therefore the abstract should be thoroughly assessed for relevance, validity, reliability and academic contribution in relation to the financial implications of translating the study.
Intervention: - Reflexology therapy as standardised stand-alone intervention described in detail to comply with the theoretical definition of study - Reflexologist/therapist to manually stimulate precision reflex points/zones on the feet, hands, ear, face or body of the participant during intervention according to the principles of Fitzgerald, Ingham, Marquardt, Dougans or Crane - Duration of treatment should be a minimum of 30 minutes and a maximum of 60 minutes per treatment	- Reflexology treatment in combination with other CAM modalities or therapies as intervention - Over-stimulation of reflex points/zones that may exhaust the human body	- To ensure appropriate evidence of standardised reflexology technique and limit non-specific effects of other CAM modalities or combinations thereof - To create uniformity of intervention principles - To ensure sufficient stimulus to the human body to mobilise its own healing power and prevent over-stimulation of reflex points

1.4.1.3 Step3: Selecting the studies

After the formal search, the next step is the selection of relevant studies to collect evidence to answer the review question. In general, a comprehensive search strategy that identifies the maximum number of eligible primary sources together with the use of at least two to three search strategies is performed during an integrative literature review (Whittemore & Knafl, 2005:548).

All the titles and abstracts of identified studies were screened for relevance to the review question. In cases where uncertainty regarding the relevance of the studies arose, the complete original article was retrieved to thoroughly assess its relevance. An accurate record of all identified studies, the screening process and motivation of decisions for inclusion and exclusion of studies was kept for audit purposes. A second reviewer independently reviewed the identified studies of the search to limit selection bias. A manual search was performed on all the reference lists of identified studies to identify any potentially missed studies. An independent search was conducted after the formal search, using the Google search engine, to identify any missed eligible studies (Whittemore & Knafl, 2005:549).

1.4.1.4 Step 4: Performing the critical appraisal

In the integrative literature review, the sampling frame is complex and broad to include all eligible studies. Critically appraisal of the selected studies for methodological quality and validity but enhances the quality of the integrative literature review. There is no golden standard for evaluating and interpreting the quality of primary sources that are not empirical in research reviews, therefore quality evaluation of an integrative review will vary depending on the sample frame (Whittemore & Knafl, 2005:549).

In this study, all relevant studies were appraised for methodology and quality using the standardised checklists from the Critical Appraisal Skills Programme (CASP) (2006). A record of all the appraised studies, tools that have been used for appraisal, appraisal outcomes and motivation for decisions on inclusion and exclusion was kept for audit purposes. A second reviewer was asked to independently appraise the selected studies for methodological quality and inclusion in or exclusion from the integrative literature review. Any conflict that occurred during the appraisal was resolved by personal meetings and discussions

between the researcher and the independent reviewer. The assessments were recorded on a sheet of quality ratings.

1.4.1.5 Step 5: Extracting data and drafting a summary of relevant studies

Data extraction of all the relevant selected and included studies after appraisal was done according to data reduction and data display. Data reduction involves the determination of an overall classification system or sub-grouping to manage data from diverse methodologies. In the integrative literature review, the data can be classified into sub-groups based on the type of evidence, study designs, chronology, settings and sample characteristics, or predetermined conceptual classification categories such as participants' experience, attitude or behaviours (Whittemore & Knafl, 2005:550). In this study, all the relevant primary studies included for review were classified according to study design and type of evidence. Data reduction also includes techniques for extracting and coding the data from primary studies to simplify, abstract, focus and organise data into a manageable framework to compare issues, variables or sample characteristics.

Data display involves converting the extracted data from individual primary studies into a display that assembles the data from multiple primary studies according to meticulous variables. The format of the data display can be matrices, graphs, spreadsheets or charts (Whittemore & Knafl, 2005:551). The extracted data of this integrative literature review were coded on a spreadsheet to compare themes, variables and outcomes, which were displayed in table format.

1.4.1.6 Step6: Critically synthesising the findings

The critical synthesis of the individual findings of the primary studies towards a conclusion consists of data comparison, conclusion drafting and verification. Data comparison is a repetitive process of examining the data display to identify patterns, themes and relationships of the variables. The drafting of conclusions and verification thereof are on a higher level of abstraction than data comparison. The drafting of conclusions lead to translating the specific to the general. Data synthesis requires honesty, transparency and a thorough reflection and exploration from the researcher that should be verified by continuous record keeping during the whole process to enhance rigorous methodology (Whittemore & Knafl, 2005:551).

Addressing conflicting evidence is a considerable challenge and should be dealt with either by voting, comparing the frequency of significant positive findings against significant negative findings, exploring confounding variables or motivating the need for further research (Whittemore & Knafl, 2005:551).

1.4.1.7 Step 7: Contextualising the findings

Integrative literature reviews include diverse data sources that enhance a holistic understanding of the topic of interest. Combining diverse data sources is complex and challenging, but employing techniques of mixed-method or qualitative research in this process has the potential of decreasing bias and error (Whittemore & Knafl, 2005:552). Contextualising the findings of an integrative literature review with regard to the utilisation of reflexology in adults with chronic disease to the South African context is a challenge that depends on the various findings and conclusions. This may guide future research in the South African context on the provision of more accessible, comprehensive and interactive health care to adults with chronic disease to empower caregivers and patients to manage the disease under nursing supervision.

1.5 RIGOUR

The integrative literature review was performed according to the steps of a systematic literature review to limit bias and enhance rigour. Whittemore and Knafl (2005:548) provide a strategy to enhance rigour in integrative reviews by undertaking various steps in problem identification, literature search, data evaluation, data analysis and data presentation. In this study, the strategies of Whittemore and Knafl were used to enhance rigour, as displayed in Table 1.6.

Table 1.6: Strategies to enhance rigour (adapted from Whittemore & Knafl, 2005)

Steps	Rigour concepts	Study accommodation
Problem identification	A clear identification of the problem that the review is addressing and the purpose of the review is essential to determine the variables of interest and the sample frame. Philosophical or theoretical perspectives focus the integrative review in a diverse sample frame, particularly where theoretical and empirical sources are included (Whittemore & Knafl, 2005:548).	A review question in PICOT format was formulated, as indicated under section 1.4.1 (Evans,2001:2; Melnyk & Fineout-Overholt, 2005:30). The paradigmatic perspective and theoretical concepts were described in the overview.

Steps	Rigour concepts	Study accommodation
Literature search	Well-defined literature search strategies are critical for the integrative literature review to comply with an adequate database for accurate final results. All relevant literature should be included in the review. The literature search process should be clearly documented in the methods section, including key terms, databases and search strategies. Inclusion and exclusion criteria should be determined for the primary resources to enhance rigour (Whittemore & Knafl, 2005:549).	The researcher used a well-defined search strategy that is clearly documented in the methods section under 1.4.1. A multi-stage sampling process was used. Databases were purposively selected for accessibility and appropriateness. Inclusion and exclusion criteria were set, as documented in the methods section. A comprehensive audit tool was used to audit and present the literature search.
Critical appraisal	In an integrative literature review with a diverse sample frame consisting of empirical and theoretical sources, an approach to evaluate quality similar to historical research may be appropriate. Authenticity, methodological quality, informational value and representativeness of sources need to be considered. Scores could be used as criteria for inclusion and exclusion or as a variable in the data-analysis stage (Whittemore & Knafl, 2005:550).	The researcher used an appraisal strategy according to the steps of a systematic literature review, as described under methods section 1.4.1. This strategy included the following: • Setting inclusion and exclusion criteria • Using standardised CASP instruments to enhance reliability and validity during appraisal • Using a second independent reviewer to enhance reliability and validity during appraisal, and having personal meetings to discuss results when conflicting results arise to reach consensus
Data extraction	The goals of the analysis stage are a thorough and unbiased interpretation of primary sources, along with an analysis of evidence. Extracted data are therefore compared item by item and similar data are categorised and grouped together. These coded categories are then compared, analysed and synthesised (Whittemore & Knafl, 2005:550). The primary sources included in an integrative literature review can be classified according to the type of design or evidence to promote data reduction. Reliable and valid coding procedures are essential to ensure methodological rigour. Data can then be compiled in a spreadsheet to provide organisation of the literature, which facilitates the ability to systematically compare primary sources on specific issues, variables or sample characteristics (Whittemore & Knafl, 2005:550). Data comparison involves a repertoire to identify patterns, themes or relationships (Whittemore & Knafl, 2005:551).	The researcher proposed a data-extraction strategy according to the steps of a systematic literature review under methods section 1.4.1. This includes the following: • Data reduction • Data display The extracted data of all the relevant selected studies were coded on a spreadsheet to compare themes, variables and outcomes, which are displayed in table format.

Steps	Rigour concepts	Study accommodation
Data synthesis	Conclusion drafting and verification is the final stage that moves to higher levels of abstraction and data synthesis. Data synthesis entails subsuming the specific variables of data analysis into a general conclusion . Patterns and processes are isolated and common grounds and differences are identified to put forth a generalisation. Conflicting evidence proposes vote counting as one strategy to analyse conflicting results or comparing the frequency of significant positive findings to the frequency of significant negative findings. A record should be kept during the entire process of data analysis that documents decisions, analytical thoughts, alternative hypotheses or any idea that directly relates to the interpretation of the data (Whittemore & Knafl, 2005:551).	The researcher proposed a data-synthesis strategy according to the steps of a systematic literature review under methods section 1.4.1. Critical synthesis of the individual findings of the primary studies towards a conclusion consisted of data comparison, conclusion drafting and verification. Data comparison was a repetitive process of examining the data display to identify patterns and themes of and relationships between the variables.
Presentation	Conclusions of an integrative review can be reported in table or diagrammatic format. Details from primary sources and evidence to support conclusions must be provided to ascertain a logical chain of evidence. The results should contribute to a new understanding of the phenomenon of concern and implications for clinical practice should be stated in addition to implications for research and policy initiatives. All methodological limitations of the review must be stated (Whittemore & Knafl, 2005:552–553).	The researcher plans to communicate results through the publishing of an article on the findings of the integrative literature review.

1.6 ETHICAL CONSIDERATIONS

In this study, no participants were used as sample, as primary experimental and non-experimental studies were the unit for analysis. The researcher accepted the responsibility to conduct high-quality and competent research. The proposal was submitted to the Postgraduate and Research Committee of the School of Nursing Science at the Potchefstroom campus of North-West University for approval and consent before the study was conducted. The study was supervised by two senior staff members of the School of Nursing Science at the Potchefstroom campus of the North-West University. At the North-West University (NWU) ethical review is not required for an integrative literature review (personal communication Prof. A. Kruger).

The researcher accepted the responsibility to conduct this study in an ethical manner by:

- strict adherence to the ethical principles of honesty, integrity and accuracy in reporting the studies reviewed and keeping a detailed record of review and appraisal for audit purposes;
- total abstinence from plagiarism by giving credit where it was due in the text and including bibliographic details in the list of references;
- showing respect for copyrights where and when applicable by giving credit in the text when illustrations, diagrams or statistical graphics were used from articles or books and by including bibliographic details in the list of references;
- collecting the data from sound scientific data sources that were traceable, accessible and relevant for audit purposes by keeping a well-documented record of all databases searched and search results as well as inclusion and exclusion criteria of articles; and
- following the fundamental ethical principles of respect for the information sources and databases by handling all information with confidentiality and responsibility (Brink *et al.*, 2006:40; Burns & Grove, 2005:203).

1.7 OUTLINE OF THE DISSERTATION

The dissertation was written in article format. Chapter 1 includes the background and rationale of the study, accompanied by the problem statement, purpose of the study and paradigmatic perspective of the researcher. The outline of the research design and methodology followed and it is concluded with the ethical considerations that are applicable to the study.

The research findings were described and discussed in the format of an article in chapter 2. The title of the article is:

An integrative literature review of the utilisation of reflexology in adults with chronic disease.

Chapter 3 concluded the dissertation with a description, discussion and drawing of a conclusion statement. It is followed by the recommendations and limitations of the study.

In the following statement, the co-authors confirm their role in this study and agree that the article be included in the dissertation:

Hereby I confirm that the following article be included in the dissertation. I acknowledge that my role in this study corresponds with the above mentioned role. I hereby give permission that the article may be published as part of the dissertation of Ms E. Steenkamp.



Ms B Scrooby

Prof. C. van der Walt

CHAPTER 2

ARTICLE

Full title: *An integrative literature review of the utilisation of reflexology in adults with chronic disease*

Short title: *Reflexology in adults with chronic disease*

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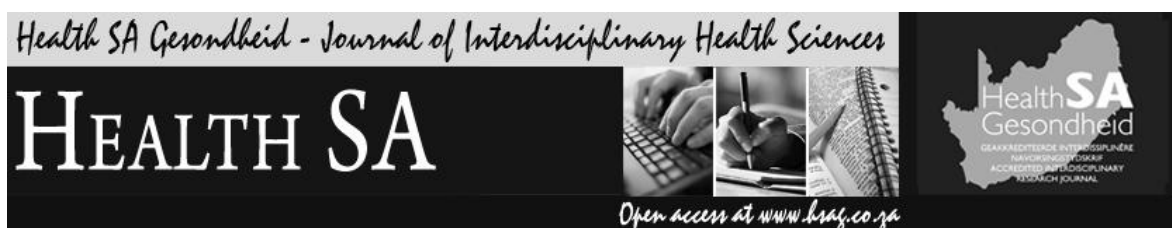
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About 20 pages text only (maximum), excluding tables, figures and the list of references.

Manuscript Guidelines

Title: Informative but concise, In small capital letters, centered and in bold, font size 14, eg.: Names of questionnaires, countries, and or authors start with capital letters.

Author: Name(s), include full first name, e.g. Gert P. Roux, not G.P. Roux. Include the name of the department and the University of each author. The e-mail address, postal and phone number of the corresponding author should be included.

Abstract: Not more than 200 words, and should state concisely the scope of the work and the principal findings:

- ☐ the objective of the study
- ☐ the population size, sampling strategy, sample size and response rate
- ☐ main statistical procedures used for analyzing the data
- ☐ most significant results of the study.

Opsomming: Always include an Afrikaans abstract of the article, please follow the same format and structure as indicate within the heading 'abstract'.

Key words: Use five [5] words not already included in the title, separated by a semi-colon.

Synopsis: Afrikaans articles (or articles in any other official SA language) must also have a synopsis of the article of between 500-600 words in English (the entire synopsis appears in italics).

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Manuscript Contents

The manuscript contains five sections, namely the introduction, research design, results, discussion and the references. All these first-level headings (except 'introduction') appear in bold capital letters and are centered.

INTRODUCTION:

The introductory section normally contains the following eight elements; headings are indicated in [brackets]:

- (1) [**Key focus of the study**] A thought-provoking introductory statement on the broad theme or topic of the research (why should I even bother to read further?);
- (2) [**Background to the study**] Providing the background or the context to the study (explaining the role of other relevant key variables in this study);
- (3) [**Trends from the research literature**] Cite the most important published studies previously conducted on this topic or that has any relevance to this study (provide a high-level synopsis of the research literature on this topic);
- (4) [**Research Objectives**] Indicate the most important controversies, gaps and inconsistencies in the literature that will be addressed by this study;

(5) In view of the above (in 4) state the core research problem and specific research objectives that will be addressed in this study;

(6) [**Ethical Considerations**]

(7) [**The potential value-add of the study**] Explanation of the study's academic (theoretical & methodological) or practical merit and/or importance (provide the value-add and/or rationale for the study); and

(8) [**What will follow**] Provide the reader with an outline of what to expect in the rest of the article.

Synthesis and Critical evaluation of the literature – Still apart of Introduction

A synthesis and critical evaluation of the literature (not a compilation of citations and references) should at least include or address the following aspects:

(1) Conceptual (theoretical) definitions of all key concepts;

(2) A critical review and summary of the themes emerging from previous research findings (constructs, research participants, research designs, objectives, etc.) on the topic;

(3) Including a review of existing approaches towards the measurement of relevant constructs; and

(4) A clearly defined link should be established between formulated hypotheses and objectives. The stated objectives follow directly on the section where the literature was reported. .

RESEARCH DESIGN

The first-level heading **RESEARCH DESIGN** is typed in capital letters, centered and in bold. Only **three** second-level headings follow on the research design and they appear in lower case, bold and are flush with the margin.

Research approach

A brief description of the research approach followed in the study should be included. It should, for instance, explain from which qualitative tradition the study is and also motivate why this approach is specifically required. The author(s) may state their scientific beliefs (ontology and epistemology) if these have an effect on the choice of the research approach.

Research methods

Under the research method the author(s) provide at least descriptions on the following third-level headings, namely: research context (setting), entrée and ethical considerations, data collection methods, recording of the data, data analyses, strategies employed to ensure data quality and reporting.

These headings are typed in italics and are flush against the margin. Fourth-level headings (italics, underlined) may be used under each of these headings (as described above).

Population Sampling

The qualitative sampling procedures used in the study, such as cueing, purposive sampling or snow-balling are described and motivated in this section.

Data collection methods

In this section the author(s) explain where the data was sourced and which data collection methods (e.g. semi-structured or unstructured interviews, focus-groups) were applied. In some instances solicited documents are also used.

Data analyses

In this case the author(s) explain which methods of data analyses were applied. Different data analyses techniques result in different variations of qualitative research.

FINDINGS & DISCUSSIONS

The next heading is **FINDINGS & DISCUSSIONS**, which appears in capital letters, bold and is centered. This section presents the results of the investigation in the sequence of the formulated objectives or formulated postulates/propositions (if applicable).

Tables and Figures are each presented on a separate page after the section **REFERENCES** and appear in the same numerical order as they appear in the text. The positions of tables or figures are indicated in the text in the following way: <include Table 1 about here>

Therefore, no tables or figures appear in the text of an article, but are each displayed on a separate page for the type setter to see as a whole. If the sizes of the table or figure are too large it can be uploaded as supplementary files in Step 4 of the submission process. It is essential that all table and figures are clearly labelled.

CONCLUSION & RECOMMENDATION

The next heading is **CONCLUSION & RECOMMENDATION**, which appears in capital letters, in bold and centred.

This section normally contains the following eight elements:

- ❑ restate the main objective of the study;
- ❑ reaffirm the importance of the study by restating its main contributions;
- ❑ summarise the results in relation to each stated research objective or research hypothesis;
- ❑ link the findings back to the literature and to the results reported by other researchers;
- ❑ provide explanations for unexpected results;
- ❑ provide the conclusion and recommendations (implications for practice);
- ❑ point out the possible limitations of the study; and
- ❑ provide suggestions for future research.

Second and third-level headings may be used.

REFERENCES

References begin on a separate page. References cited in the text should all be included in the list at the end of the paper. Full references at the end of the paper, arranged alphabetically by surname, chronologically within each name, with suffixes a, b, c, etc. to the year for more than one per year by the same author. Note that the second and subsequent lines are indented.

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ABSTRACT

This is an integrative literature review of the utilisation of reflexology as complementary and alternative treatment modality in adults with chronic disease. Anecdotal evidence has claimed potential health benefits of reflexology for patients with various chronic diseases. In this study, selected databases that were accessible were searched using keywords such as reflexology therapy, zone therapy and combinations thereof. Databases such as SA Nexus, SAePublications, ProQuest, Web of Knowledge, EBSCOhost Platform, ScienceDirect, Cochrane Library and Google Advanced Scholar were searched for primary studies and reviews of primary studies from 2000 until the end of 2008 (N = 1171). Primary experimental and non-experimental studies in any language with an abstract in English were identified. Only studies that complied with the inclusion criteria were reviewed and appraised (n = 35) for study quality with appropriate tools from the Critical Appraisal Skills Programme (CASP) and the American Dietetic Association's (ADA) Evidence analysis manual. Evidence extraction, analysis and synthesis were done to review available evidence by means of the evidence class rating and evidence grading of strength prescribed in the ADA's manual. Study findings represent a statistical significant reduction in the frequency of seizures of patients with intractable epilepsy, an improvement of sensory and urinary symptoms associated with multiple sclerosis and a clinical significant reduction of pain and anxiety in patients with cancer and fibromyalgia syndrome to increase overall well-being and quality of life. No statistical significant evidence was reported on benefits of reflexology for irritable bowel syndrome, menopausal symptoms, chronic low back pain and asthma. Thus there appears to be fair evidence of the effectiveness of reflexology, in addition clinical evidence supports the utilisation of reflexology to promote well-being and quality of life in adults with chronic disease.

KEYWORDS:

Reflexology; integrative literature review; chronic disease.

OPSOMMING

Hierdie studie behels 'n geïntegreerde literatuuroorsig oor die gebruik van refleksologie as 'n modaliteit van aanvullende en alternatiewe behandeling in volwassenes met chroniese siektes. Beskikbare anekdotiese bewyse bepaal dat refleksologie moontlike voordele vir verskeie chroniese siektes inhou. In hierdie studie is 'n soektog geloods deur doelbewus geselekteerde databasisse waartoe toegang verkry kon word met behulp van sleutelwoorde soos refleksologie-terapie, soneterapie en kombinasies daarvan te deursoek. Databasisse soos SA Nexus, SAePublications, ProQuest, Web of Knowledge, EBSCOhost Platform, ScienceDirect, Cochrane Library en Google Advanced Scholar is deursoek vir primêre studies en literatuur oorsigtelike samevattinge van primêre studies vanaf 2000 tot die einde van 2008 (N = 1171). Eksperimentele en nie-eksperimentele studies in enige taal met 'n opsomming in Engels is geïdentifiseer. Indien dit aan die bepalings van die insluitingskriteria voldoen het (n = 35), is die gehalte nagegaan en beoordeel aan die hand van toepaslike instrumente van die *Critical Appraisal Skills Programme* (CASP) en die *American Dietetic Association (ADA) se Evidence analysis manual*. Die onttrekking, ontleding en sintese van bewyse is gedoen ten einde 'n ge-integreerde literatuur oorsig te bied van beskikbare bewyse deur middel van die beoordeling van bewysklas en gradering van bewyssterkte, soos in die ADA se handleiding voorgeskryf. Studie bevindings verteenwoordig 'n statistiese beduidenisvolle verlaging in die frekwensie van konvulsiesby pasiënte met epilepsie, 'n verbetering van sensoriese en urinêre simptome ge-assosieer met veelvuldige sklerose en 'n kliniese beduidenisvolle afname in angstigheid en pyn by pasiënte met kanker en fibromialgiese sindroom om algehele welstand en kwaliteit van lewe te verbeter. Geen statisties beduidende getuienis is gevind aangaande voordele van refleksologie vir ge-irriteerde derm-sindroom, menoposale simptome, kroniese lae rugpyn en asma nie. Dit blyk dat daar redelike bewyse bestaan vir die effektiwiteit van refleksologie, daarbenewens steun kliniese bewyse die gebruik van refleksologie om welstand en gehalte van lewe te bevorder in volwassenes met kroniese siektes.

SLEUTELWOORDE:

Refleksologie; geïntegreerde literatuuroorsig; kroniese siektes.

2.1 INTRODUCTION

The purpose of this study was to explore and describe identified scientific evidence of the utilisation of reflexology as CAM modality to promote well-being and quality of life in adults with chronic disease.

In the practice of comprehensive nursing care, nurses are often confronted with inquiries from patients regarding information on, accessibility to and provisioning of CAM modalities such as reflexology, acupuncture and therapeutic touch. Patients request advice on CAM modalities and highly value the opinion of a trusted nurse in this regard; they expect nurses to be able to react informatively to these inquiries. However, it still appears to be an unfamiliar territory to nurses.

2.1.1 Complementary and alternative medicine

Complementary and alternative medicine is a term that covers a broad range of over a hundred philosophies, approaches, therapeutic modalities and healing practices that conventional medicine does not commonly study, understand, use or make available to patients. These therapies are often used in combination with conventional medicine and are then referred to as complementary (Koithan, 2009:18).

CAM has become increasingly popular over the last decade in the USA, the UK and Australia (Lee *et al.*, 2004:655; Libster, 2001:121; Mackereth *et al.*, 2000:66). The use of CAM and specifically reflexology has always been common among Chinese and other Asian patients in countries such as Singapore, Hong Kong and Taiwan and is influenced by these countries' psychosocial philosophies, value systems and cultural beliefs (Lee *et al.*, 2004:656). Even in South Africa, the use of CAM is becoming more popular, as revealed by a cross-sectional survey conducted in 2005 in Pretoria among HIV-infected patients (Malangu, 2007:273).

It is a commonly held belief that patients often use CAM when they are dissatisfied with conventional medicine, when it is too costly, impersonal, has too many side effects or seems to be ineffective. However, it has been stated by Lee *et al.* (2004:656), that CAM offers patients an alternative model that is more appropriate and comfortable to fit their personal value system and cultural beliefs. Patients use CAM during chronic disease to cope with the various symptoms as a self-care management tool. They do not reject conventional care as such, but use CAM complementary to conventional care (Thorne *et*

al., 2002:671). Reflexology is one of the CAM modalities that are frequently used in this way (Mackereth *et al.*, 2000:66).

Reflexology is a regulated practice in many countries. In South Africa, the practice of reflexologists is regulated by the Allied Health Professions Council in terms of the Allied Health Professions Act 63 of 1982, as amended by the Chiropractors, Homeopaths and Allied Health Service Professions Act in the Second Amendment Act 50 of 2000 (South Africa, 1982; South Africa, 2000).

In the high-tech world of health care, a number of CAM modalities use principles of energy transformation and manipulation to enhance vitality and well-being in individuals. Reflexology is a CAM modality that entails a non-invasive therapeutic intervention, performed manually with the hands and fingers of the therapist to stimulate precision reflex points/zones on the feet, hands, face, ears or body of the individual to balance the vital energy or life force in the human body so as to promote health, vitality and well-being (Amster *et al.*, 2000:80; Libster, 2001:121; Mackereth *et al.*, 2000:70). Treatment duration should not be less than 30 minutes and not more than 60 minutes to provide sufficient stimuli to the human body to mobilise its own healing powers and to prevent over-stimulation of the human body (Dougans, 2005:250–254; Gillanders, 2005:12; Mackereth & Tiran 2002:5).

Energy manipulation and stimulation are concepts that configure strongly along with relaxation as a possible explanation for the effects of reflexology on vitality and well-being in patients (Carpenter & Neal, 2005:115). The most popular theory among reflexologists appears to be the meridian theory, which is based on principles of traditional Chinese medicine (Crane, 1997:5; Dougans, 2005:36; Mackereth & Tiran, 2002:12). The meridian theory suggests that vital energy, called “chi”, flows in channels, called meridians, throughout the human body from top to toe and vice versa. These meridians often follow the line of a neural pathway or blood vessel. If the body, mind and spirit are in equilibrium, the energy flows freely, but disease, pain or stress results in energy changes that lead to imbalances in energy and stagnancies thereof. Reflexology is one means of rebalancing the “chi” by unblocking, stimulating or sedating the energy flow through direct stimulation of the reflex points on the feet, body, ears or hands (Crane, 1997:50; Dougans, 2005:36; Mackereth & Tiran, 2002:11).

Dougans (2005:20), an authority on reflexology, is of the opinion that reflexology offers a large scope of benefits to individuals that suffer from chronic diseases. Dougans (2005:11-

13) explains that chronic diseases are the result of energy blockages, stagnancies and imbalances in the meridians of the human body. These energy imbalances and stagnancies deprive the human body of vitality and well-being and are most often the forerunners of more serious organ and system disorders. Reflexology stimulates the corresponding reflex points on the soles of the feet in order “to open these energy stagnancies and blockages along the meridians” to enhance vitality and well-being in the organs of the human body (Dougans, 2005:12).

2.1.2 Chronic disease

Smeltzer et al. (2008:166) define chronic disease as chronic conditions that have a prolonged course of at least three months that do not resolve spontaneously and for which complete cures are rare. Chronic diseases such as cardiovascular diseases, diabetes mellitus, stroke, Aids and tuberculosis are relatively common in South Africa (Connor *et al.*, 2005:334). In South Africa there appears to be an increase in chronic diseases, especially in relation to the high incidence of HIV in sub-Saharan Africa (Bryer, 2008:151; Connor *et al.*, 2005:334; Modi *et al.*, 2006:1247). Tuberculosis, cardiovascular disease and stroke place a tremendous burden on health care systems, especially in combination with the HIV/Aids epidemic (Connor *et al.*, 2004:627; Norman *et al.*, 2006:12).

Chronic infectious diseases, such as HIV/Aids and tuberculosis, which are paralleled by the increasing threat of non-communicable chronic diseases, add to the burden disease in South Africa.

In South Africa, sedentary life style, smoking, obesity and alcohol abuse are of the most important lifestyle-related risk factors for chronic diseases such as diabetes mellitus, hypertension and cardiovascular disease (Bryer 2008:151–152; Groenewald *et al.*, 2007:674). Chronic kidney disease shares common risk factors, such as smoking, hypertension, diabetes, obesity and hyperlipidaemia, with cardiovascular disease and stroke (Connor *et al.*, 2005:335; Katz *et al.*, 2007:360).

The characterised risk factors of cultural habits and lifestyle in South Africa mould a bottomless grave to health, vitality and well-being and promote low quality of life. Chronic disease can result from a secondary complication of acute illness, genetic factors, injury or unhealthy lifestyle behaviours. The management of chronic diseases entails coming to terms with personal identity and lifestyle changes to prevent further complications, to

alleviate symptoms and cope with disabilities and to adapt to the overall impairments and disabilities of the chronic disease concerned.

Chronic disease firstly interferes with the activities of daily living and secondly with the overall quality of life of the individual. Individuals that suffer from ruthless chronic disease may become totally or partially dependent on caregivers to perform the routine activities of daily living due to poor vitality and impaired well-being. The symptoms of chronic disease can be alleviated by conventional medicine and comprehensive health care, but place a high burden on health care provisioning. Furthermore, chronic deterioration often occurs, which places considerable stress on the individual's energy, vitality and well-being (Smeltzer *et al.*, 2008:167).

2.1.3 Problem Statement

Reflexology claims to address the energy reserves of the human body to promote vitality and well-being by balancing the energy imbalances in the human body. Several studies have been conducted on the effectiveness of reflexology in various chronic diseases, but a major concern has been the inappropriate methodological quality and small sample size in these studies, which lead to insignificant statistical results (Huntley & Ernst, 2000:104). Carpenter and Neal (2005:116) recommend that more research be conducted on the utilisation, understanding and knowledge base of reflexology during chronic disease so as to collect more evidence-based data. Mackereth *et al.* (2000:71) state that there is a growing number of people accessing reflexology in a variety of health care and private settings, and that health professionals should therefore consider expanding and developing their practice by undertaking research on this matter in order to gain evidence-based knowledge to make informed decisions regarding access to and provisioning of reflexology as CAM modality to patients during integrative health care. The theory of the underlying action and mechanism of reflexology is still open for debate due to the paucity of formal research data on this matter.

The few randomised control studies that have been conducted on the effectiveness of reflexology in chronic disease apparently used very small numbers of subjects, inappropriate designs and weak measures of critical outcomes (Carpenter & Neal, 2005:116; Huntley & Ernst, 2000: 104). It seems that future studies should be conducted with more attention to the methodological aspects of rigorous research to determine the potential benefits of reflexology in chronic disease, if any. A number of research studies

indicate consensus on an overall view of the benefit of reflexology to vitality and well-being in individuals by improvements in poor blood circulation, fatigue, constipation, anxiety, loss of appetite and poor coping mechanisms (Brown & Lido, 2008:130; Gunnarsdottir, 2007:219–223; Hiroyuki, Takako, Yoko, Hiroshi, Hiroyasu & Tatsuya, 2004:795; Walsh & Wilson, 1999:35). Studies conducted on pain relief, pain control and anxiety in patients suffering from cancer and dementia showed a positive outcome when reflexology therapy was offered to these patients (Hodgson & Andersen, 2008:269; Stephenson, Weinrich & Tavakoli, 2007:127).

The utilisation of reflexology in chronic disease should therefore be explored, as there appears to be an increasing interest in complementing conventional care with reflexology during chronic disease. Studies should include both quantitative and qualitative approaches to enhance the total understanding and utilisation of reflexology during chronic disease as community-driven self-help management and care (Ebey-Tessendorf, Kretzmann & Mouton, 1997:20; Lee *et al.*, 2004:655; Libster, 2001:121; Mackereth *et al.*, 2000:66).

There appears to be considerable anecdotal evidence and expert opinion in the literature on the benefits of reflexology in chronic disease but the question remains what these benefits are and what scientific evidence exists to guide evidence-based nursing practice.

2.1.4 Research question

The research question that arises is:

What evidence exists on the utilisation of reflexology as CAM modality in adults with chronic disease?

The purpose of this study was to explore and describe identified scientific evidence of the utilisation of reflexology as CAM modality to promote well-being and quality of life in adults with chronic disease.

2.1.5 Theoretical definitions

The theoretical concepts used in this study are displayed in Table 2.1 for more clarity and to guide the process of the integrative literature review.

Table 2.1: Theoretical definitions of the study

Adult	A person that is a grown-up or has reached maturity. One who is over the age stated by the law, usually 18 years (NEUD, 2001:11).
Chronic disease	Medical conditions or health problems with associated symptoms or disabilities that have a prolonged course of at least three months, that do not resolve spontaneously and for which complete cures are rare (Smeltzer <i>et al.</i> , 2008:166).
Reflexology therapy	A CAM modality that consists of a non-invasive therapeutic intervention, performed manually with the hands and fingers of the reflexologist to stimulate precision reflex points/zones on the feet, hands, face, ears or body of the individual to balance the vital energy or life force in the human body so as to promote health, vitality and well-being. Stimulation should be performed according to the principles of Fitzgerald, Ingham, Marquardt, Dougans or Crane. Treatment duration should not be less than 30 minutes and not more than 60 minutes to provide sufficient stimuli to the human body so as to mobilise its own healing powers and prevent over-stimulation of the human body (Dougans, 2005:250–254; Gillanders, 2005:12; Mackereth & Tiran, 2002:5).
Utilisation	To make use of or exploit (OWD, 2006:781).
Abbreviations	<i>Mosby's Medical Dictionary (MMD)</i> <i>New English Usage Dictionary (NEUD)</i> <i>Oxford Wordpower Dictionary (OWD)</i>

2.1.6 Potential added value of the study

An exploration and description of identified scientific evidence of the utilisation of reflexology as CAM modality to promote well-being and quality of life in adults with chronic disease may help South African nurses to better understand the value of reflexology as a complementary modality in adults with chronic disease. Reflexology may also contribute to community health care by empowering the individual to use reflexology as a self-care tool to manage and cope with chronic disease symptoms.

2.1.7 Ethical consideration

In this study, no participants were used as sample, as primary experimental and non-experimental studies were the unit for analysis. The researcher accepted the responsibility

to conduct high-quality and competent research. The proposal was submitted to the Postgraduate and Research Committee of the School of Nursing Science at the Potchefstroom campus of North-West University for approval and consent before the study was conducted. The study was supervised by two senior staff members of the School of Nursing Science at the Potchefstroom campus of the North-West University. At the North-West University (NWU) ethical review is not required for an integrative literature review (personal communication Prof. A. Kruger).

The researcher accepted the responsibility to conduct this study in an ethical manner by:

- strict adherence to the ethical principles of honesty, integrity and accuracy in reporting the studies reviewed and keeping a detailed record of review and appraisal for audit purposes;
- total abstinence from plagiarism by giving credit where it was due in the text and including bibliographic details in the list of references;
- showing respect for copyrights where and when applicable by giving credit in the text when illustrations, diagrams or statistical graphics were used from articles or books and by including bibliographic details in the list of references;
- collecting the data from sound scientific data sources that were traceable, accessible and relevant for audit purposes by keeping a well-documented record of all databases searched and search results as well as inclusion and exclusion criteria of articles; and
- following the fundamental ethical principles of respect for the information sources and databases by handling all information with confidentiality and responsibility (Brink *et al.*, 2006:40; Burns & Grove, 2005:203).

2.2 RESEARCH DESIGN

The design of this study is descriptive in nature and is aimed at exploring and describing the identified scientific evidence of the utilisation of reflexology as CAM modality to promote well-being and quality of life in adults with chronic disease by means of an integrative literature review.

2.2.1 Integrative literature review

The integrative literature review was conducted by following the steps of a systematic literature review to enhance rigour. The seven steps of the systematic literature review that were followed are displayed in Table 2.2.

Table 2.2: Steps of systematic literature review adapted to conduct integrative literature review

1	Formulating the review question: •The question is formulated according to the PICOT format. ○ Patient/population of interest ○ Intervention ○ Comparison (if applicable) ○ Outcome ○ Time (if applicable)
2	Generating a search strategy: • Identifying keywords for the search. • Setting inclusion and exclusion criteria. • Deciding on databases. • Deciding on inclusion of grey literature. • Selecting language. • Setting timeframe of studies to be used.
3	Selecting the studies: • Initial screening process: Reading the titles and abstracts for relevance. • Accurate record keeping of all identified studies and the initial screening process for audit purposes. • Manual searching of all the references of identified studies to identify potentially missed studies. • Selecting all relevant studies according to selection criteria. • Retrieving full-text articles of all relevant studies. • Classifying relevant studies by type of research design. • Accurate record keeping of included and excluded studies for audit purposes. • Creating a sort list of relevant studies included for critical appraisal by indicating author, reference, title, study design, sample, data collection and analysis, quality rating and comments.

4	Performing the critical appraisal: • Completing evidence worksheets. • Assessing methodological quality and validity using appropriate criteria. • Recording assessments on a sheet of quality ratings.
5	Extracting data and drafting a summary of all relevant studies: • The relevant studies are those that comply with the selection criteria and that were found to be of good quality.
6	Critically synthesising the findings.
7	Contextualising the findings: • The findings are contextualised to the South African context

2.2.1.1 Review question

The formulation of an appropriate review question is necessary to focus the integrative literature review and to identify relevant primary studies on the subject during the search.

According to Evans (2001:2) and Melnyk and Fineout-Overholt (2005:30), the review question should consist of the following components: **P**atient/population, **I**ntervention, **C**omparison (if applicable), **O**utcome and **T**ime (if applicable). The integrative literature review question has been transcribed in PICOT format, as displayed in Table 2.3.

Table 2.3: Review question in PICOT format

P	I	C	O	T
Adults with chronic disease	Standardised reflexology therapy (as CAM modality) on precision reflex points/zones according to the principles of Fitzgerald, Ingham, Marquart, Dougans or Crane	Conventional health care	To promote well-being and quality of life	Reflexology treatment 30 to 60 minutes' duration

Search strategy (sampling)

The unit of analysis for this integrative literature review was all primary studies and reviews of primary studies on the utilisation of reflexology in adults with chronic disease, within the timeframe January 2000 to December 2008, to ensure that recent research is identified.

In order to identify the most relevant, high-quality research on the topic of interest that answers the review question appropriately, inclusion and exclusion criteria were determined, as adapted from the American Dietetic Association (ADA) (2005:13). The population was identified as adults 18 years and older, to exclude babies, children and adolescents. The setting was selected as conventional, primary, tertiary and palliative institutional health care settings, complementary and alternative health care settings and the community, to accommodate adults with chronic disease. The language of studies was selected as any language with English abstracts, to limit publication bias. The intervention was defined as reflexology as a stand-alone CAM modality according to the principles of Fitzgerald, Ingham, Marquart, Dougans or Crane with a duration of 30 to 60 minutes, to provide sufficient stimulation of precision reflex points and prevent over-stimulation of the human body (Dougans, 2005:250–254; Gillanders, 2005:12; Mackereth & Tiran, 2002:5).

The following combination of databases was selected on the basis of appropriateness and accessibility. These databases were freely available and cover the field of CAM, nursing science, conventional medicine and formally published research studies. Keywords such as complementary and alternative medicine, reflexology therapy, zone therapy and foot massage and combinations thereof were used in the search.

Studies are not always published as full papers in peer-reviewed journals, and may be published as posters, reports, theses and conference abstracts. Therefore, all sources were included in the search strategy.

The databases and various keywords that were used in the search are displayed in Table 2.4:

Table 2.4: Databases with keyword combinations used in search

Database / Platforms	Subdivisions	Keywords
SA Nexus (National Research Foundation [NRF])	Completed and current research in SA	Complementary and alternative medicine AND reflexology therapy

Database / Platforms	Subdivisions	Keywords
ProQuest	International theses and dissertations	Complementary and alternative medicine reflexology therapy
Web of Knowledge	Web of science	Reflexology OR zone therapy
SAePublications	South African journals	Reflexology OR zone therapy
EBSCOhost Platform	Academic Search Premier Africa-Wide: NiPAD CINAHL Health Source: Nursing/Academic Medline PsychInfo	Reflexology therapy OR zone therapy NOT foot massage
Cochrane Library	CDSR (Cochrane Database Systematic Reviews) CCRT (Cochrane Central Register of Controlled Trials) DARE (Database of Abstracts of Reviews of Effects)	Reflexology therapy
Database	Subdivisions	Keywords
ScienceDirect	Life sciences Health sciences Social sciences and humanities	Reflexology OR zone therapy
Google (Advanced Scholar Search)	Medicine Pharmacology and veterinary science	Reflexology therapy in adults suffering from chronic disease

2.2.1.3 *Selection of studies*

Study selection is usually conducted by an initial screening process of all titles and abstracts of identified studies to determine relevancy to the review question and to refine the search strategy. Accurate record keeping has been conducted throughout the process for audit purposes to enhance rigour and is available on request, as described in the manual of the Centre for Reviews and Dissemination (CRD) (2009:23).

Studies that appear to meet the inclusion criteria were selected and full papers of these studies were retrieved to thoroughly assess the relevancy. Study review and selection were undertaken by the first author and second author of the research project. Accurate record keeping of the study review and selection process was conducted for audit purposes and to enhance rigour of the research project.

The electronic database search identified a total of 1 171 studies. All titles and abstracts were screened for relevance and 888 studies were excluded. The remaining 283 abstracts

and titles of studies were screened for the second time to include only studies relevant to the utilisation of reflexology as CAM modality in adults with chronic disease. Another 201 studies were excluded. The remaining 82 studies were screened for duplicates and 31 duplicates were excluded, leaving 51 studies for retrieval of full-text articles. The study selection for formal review and critical appraisal is displayed in Flow diagram2.1.

The researcher attempted to retrieve full-text articles of these 51 studies to thoroughly review the evidence. Unfortunately, the researcher had to exclude a further 16 studies during this step as a result of studies that were in foreign languages unfamiliar to the researcher. After reassessment of the English abstracts and consultation with the supervisors, the researcher decided to exclude the particular studies, as the study populations concerned differed in many ways with regard to disease typology, social customs, culture and habitat from the South African context. A further motivation was incomplete English abstracts, small sample size and insignificant statistical results that recommended further research in this area. The excluded studies are displayed in Table 2.5.

Flow diagram 2.1: Study selection process

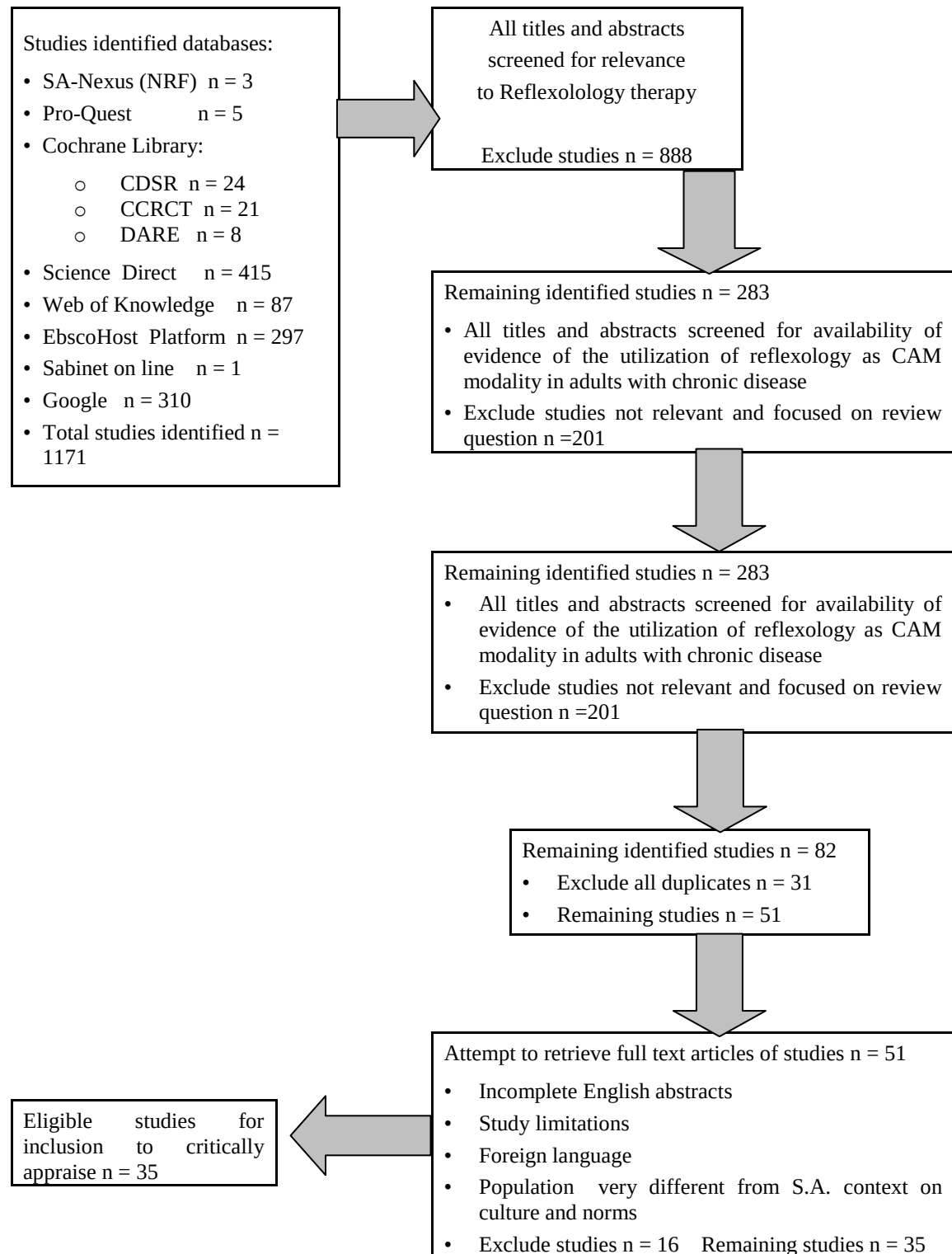


Table 2.5: Studies excluded due to foreign language

Author and journal details	Title
Cho, G.Y. & Park, H.S. 2004. <i>J Korean Academic Fundamental Nursing</i> 11(2):138–147	Effects of 6-week foot reflexology on the blood pressure and fatigue in elderly patients with hypertension
Degam M., Fabris F., Vanin F., Bevilacqua M., Genova V. 2000. <i>Problemi della professione infermieristica</i> 53(2):80–87	The effectiveness of foot reflexology on chronic pain associated with a herniated disk
Jin, S.J. & Kim, Y.K. 2005. <i>J Korean Academic Adult Nursing</i> 17(3):493–502	The effects of foot reflexology massage on sleep and fatigue of elderly women
Kang, H.S. 2004. <i>J Korean Academic Adult Nursing</i> 16(3):482–492	The effects of self-foot reflexology on urinary incontinence in middle-aged women
Kim, K.S. 2003. <i>Korean J Rehabilitation Nursing</i> 6(2):152–163	Effect of foot reflex massage on stress responses, and glucose level of non-insulin dependent diabetes mellitus patients
Kim, K.S., Sea, H. & Kang, J. 2000. <i>J Rehabilitation Nursing</i> 3(1):108–117	The effects of community based self-help management program on the activity of daily life, muscle strength, depression and life satisfaction of post-stroke patients
Lee, Y.M. & Sohng, K.Y. 2005. <i>Kanho Hakhoe Chi</i> 35(7):1221–1228	The effects of foot reflexology on fatigue and insomnia in patients suffering from coal workers' pneumoconiosis
Lee, Y.M. 2006. <i>J Korean Academic Nursing</i> 36(1):179–188	Effect of self-foot reflexology massage on depression, stress responses and immune functions of middle aged women
Oh, H.S. & Ahn, S.A. 2006. <i>J Rehabilitation Nursing</i> 9(1):25–33 Jun.	The effects of foot reflexology on pain and depression of middle-aged women with osteoarthritis
Oh, S.Y. 2002. <i>J Korean Academic Fundamental Nursing</i> 9(2):213–225	The effects of hand reflexology on Saeng-chi and immunity in ESRD patients
Park, H.S. & Cho, G.Y. 2004. <i>J Korean Academic Nursing</i> 34(5):739–750	Effects of foot reflexology on essential hypertension patients
Song, M.R. & Song, H.M. 2005. <i>J Rehabilitation Nursing</i> 8(2):139–148	The effects of foot reflexology on ADL and fatigue in stroke patients
Won, J.S., Jeong, I.S., Kim, J.S. & Kim, K.S. 2002. <i>J Korean Academic Fundamental Nursing</i> 9(1):16–26	Effect of foot reflexology on vital signs, fatigue and mood in cancer patients receiving chemotherapy
Yang, J.H. 2005. <i>J Korean Academic Nursing</i> 35(1):177–185	The effects of foot reflexology on nausea, vomiting and fatigue of breast cancer patients undergoing chemotherapy
Zhao, F-M. & Chen, Q-W. 2006. <i>Chinese Journal of Clinical Rehabilitation</i> 10(39):16–17	Palma massage in the treatment of insomnia in elder inpatients
Zhong Wenyan, E.T. 2000. <i>China Reflexology Journal</i> 4:6	Observation of the therapeutic effect in treating irritable bowel syndrome with reflexology in combination with abdominal massage

Full-text articles of the remaining 35 studies were successfully retrieved and a sort list (Appendix A) was created for critical appraisal. The first author and an independent reviewer reviewed all 35 studies of the sort list for inclusion or exclusion for critical appraisal. All decisions were motivated and listed during the review on the sort list. A total of 14 studies were excluded during the review of the full articles, due to the fact that the evidence was either:

- on the utilisation of CAM in general for chronic disease;
- anecdotal knowledge or expert opinion;
- on reflexology in combination with other CAM modalities and not a stand-alone modality;
- on reflexology interventions lasting shorter than 30 minutes; or
- on reflexology interventions that are poorly described or unclear with regard to intervention duration and principles.

Studies that were excluded after the formal review are displayed in Table 2.6.

Table 2.6: Articles excluded after review, with exclusion rationale

AUTHOR	TITLE	DESIGN	EXCLUSION RATIONALE
Carpenter, J.S. & Neal, J.G. 2005. <i>The American Journal of Medicine</i> 118(12B):109S–117S.	Other complementary and alternative medicine modalities: Acupuncture, magnets, reflexology and homeopathy	Narrative review	Evidence on CAM in general; mostly acupuncture studies. Reference: Reflexology x 1 article
Esmonde, L. & Long, A.F. 2008. <i>Complementary Therapies in Clinical Practice</i> 14(3):176–184	Complementary therapy use by persons with Multiple Sclerosis: Benefits and research priorities	Qualitative survey, interactive workshop	Evidence of CAM in general as used by persons with multiple sclerosis
Gunter, A. Van Eeden, I. & De Jager, L. <i>Interdisciplinary Journal</i> 6(1):24–36	Reflexology versus reflexology and colour therapy combined for treating chronic sinusitis	Experimental design, non-equivalent control group, Before and after study	Unknown duration of reflexology intervention and poor description of intervention – not compliant with inclusion criteria or theoretical definition of reflexology
Heatley, D.G., McConnell, K.E., Kille, T.L. & Levenson, G.E. 2001. <i>Otolaryngology Head Neck Surgery</i> 125(1):44–48	Nasal irrigation for the alleviation of sinonasal symptoms	Randomised controlled trial (RCT)	Incomplete description of reflexology intervention and short duration of reflexology intervention (9 minutes per day) – not compliant with inclusion criteria or theoretical definition of reflexology
Huntley, A. & Ernst, E. 2000. <i>Complementary Therapies in Medicine</i> 8(2):97–105	Complementary and alternative therapies for treating multiple sclerosis symptoms: A systematic review	Systematic review	Evidence on CAM, not reflexology alone. Reference: Reflexology x 1 article
Magill, L. & Berenson, S. 2008. <i>Palliative & Supportive Care</i> 6(3):289–296	The conjoint use of music therapy and reflexology with hospitalized advanced stage cancer patients and their families	Qualitative case reports x 2	Reflexology not as stand-alone modality but in combination with music therapy
Milligan, M., Fanning, M., Hunter, S., Tadjali, M. & Stevens, E. 2002. <i>International Journal of Palliative Nursing</i> 8(10):489–496	Reflexology audit: Patient satisfaction, impact on quality of life and availability in Scottish hospices	Non-experimental survey (patient satisfaction), snapshot survey	Unknown duration of reflexology intervention and poor description of intervention – not compliant with inclusion criteria or theoretical definition of reflexology
Nicholas, P.K., Kemppainen, J.K. & Carnaval, G.E. 2007. <i>AIDS Care</i> 19(2):179–189	Symptom management and self-care for peripheral neuropathy in HIV/AIDS	Experimental, descriptive, cross-sectional design	Evidence of type of CAM in general as most popular self-care strategy for neuropathy in HIV
Ross, C.S.K., Hamilton, J., Macrae, G., Docherty, C., Gould, A. & Cornbleet, M.A. 2002. <i>Palliative Medicine</i> 16:544–545	A pilot study to evaluate the effect of reflexology on mood and symptom rating of advanced cancer patients	RCT	Unknown duration of reflexology intervention and poor description of intervention – not compliant with inclusion criteria or theoretical definition of reflexology; high attrition rate 35%

AUTHOR	TITLE	DESIGN	EXCLUSION RATIONALE
Schoolmeesters, L.J. 2005. The effect of reflexology on self-reported joint pain. Frances Payne Bolton School of Nursing: Case Western Reserve University (DPhil - dissertation)	The effect of reflexology on self-reported joint pain	RCT	Short duration of reflexology intervention (1 X 15 minute intervention) – not compliant with inclusion criteria or theoretical definition of reflexology
Sheldon, L.K., Swanson, S., Dolce, A., Marsh, K. & Summers, J. 2008. <i>Clinical Journal of Oncology Nursing</i> 12(5):789–797	Putting evidence into practice: Evidence-based interventions for anxiety	Review	Evidence on different CAM interventions, not reflexology alone. Reference: Reflexology x 2 articles
Vickers, A.J. & Cassileth, B.R. 2001. <i>The Lancet Oncology</i> 2(4):226–232	Unconventional therapies for cancer and cancer- related symptoms	Review	Explanation of various CAMs for cancer symptoms; anecdotal evidence and expert opinion. Reference: Reflexology x 1 article
Wright, S., Courtney, U., Donnelly, C., Kenny, T. & Lavin, C. 2002. <i>Complementary Therapies in Nursing and Midwifery</i> 8:69–76	Clients' perceptions of the benefits of reflexology on their quality of life	Non-experimental, descriptive and retrospective study	Anecdotal findings as concluded by author
Wyatt, G., Sikorsjii, A., Siddiqi, A. & Given, C.W. 2007. <i>Oncology Nursing Forum</i> 34(3):635–642	Feasibility of a reflexology and guided imagery intervention during chemotherapy: Results of a quasi-experimental study	Quasi-experimental exploratory	Reflexology not as stand-alone CAM intervention but in combination with other CAM modalities

1.4 Critical appraisal

The sort list was recompiled using study design as organiser to create the final sort list of the remaining 21 studies for critical appraisal by the researcher and independent reviewer. The completion of a specific evidence worksheet for each study individually was a requisite for critical appraisal, as recommended by the American Dietetic Association evidence Analysis Manual (ADA, 2005:54). Each study was critically appraised according to an evidence worksheet that was filed with the full-text article for audit purposes.

The outcome of appraisal is discussed accordingly. In the context of evidence-based practice, evidence from a high-quality, recent systematic review of randomised clinical trials (RCTs) is usually regarded as the strongest evidence on which to base decisions regarding efficiency (Melnik & Fineout-Overholt, 2005:11).

As the researcher departs from a naturalistic research paradigm, both experimental and non-experimental studies were included to explore and describe the utilisation of

reflexology in adults with chronic disease, therefore critical appraisal is of major importance to select studies of good quality to answer the review question appropriately.

Evidence was analysed in accordance with the evidence class rating recommended by the ADA to enhance rigour of the study (ADA 2005:17). The classes of evidence have been adapted to comply with the current nursing study, and are displayed in Table 2.7.

Table 2.7: Classes of evidence (adapted from ADA, 2005:17)

Primary reports of new data collection		Reports that synthesise or reflect on collections of primary reports	
A	RCT	M	Meta-analysis or systematic review Decision analysis Cost-benefit analysis Cost-effectiveness study
B	Cohort study		
C	Non-randomised trial with concurrent or historical controls Case-control study Study of sensitivity and specificity of a diagnostic test Population-based descriptive study Time series	R	Narrative review Consensus statement Consensus report
D	Cross-sectional study Case series Case report Before and after study	X	Health expert opinion

The included studies were also appraised for reliability, validity and credibility by means of the appropriate criteria of the Critical Appraisal Skills Programme (CASP) to determine whether the findings can be considered as good-, medium- or low-quality evidence (CASP, 2006). The scoring system of the CASP was adapted as follows by the authors for inclusion and exclusion purposes after critical appraisal:

High-quality rating: $\geq 8/10$

Medium-quality rating: $\geq 5/10$ to $< 8/10$

Low-quality rating: $\geq 1/10$ to $< 5/10$

The authors decided to include only studies with a quality rating of $\geq 5/10$ for review. The methodological quality of included studies was assessed according to research design on the basis of the appropriate criteria. Various appraisal tools were examined on the internet, such as those of the Health Evidence Bulletins of the universities of Wales and Salford, but CASP appraisal tools were chosen due to their appropriateness and accessibility. Most of the other appraisal tools seem to be adaptations of the CASP programme. Appraisal was done independently by the first author and the independent reviewer.

The first author appraised the included studies for evidence review a second time on the basis of the criteria, as recommended by the American Dietetic Association Evidence analysis manual (ADA, 2005:26–33; ADA 2009:42-46), to compare quality ratings and to promote consistency of quality ratings of studies included for evidence analysis. The authors used and compared the 2005 and 2009 editions of the ADA Evidence analysis manuals as the 2009 edition has come to their knowledge after the appraisal of the primary studies with the original 2005 edition. All checklists were completed and filed for audit purposes. The comparison of the quality rating system of the ADA (2005:26–33) and the CASP scores are displayed in Table 2.8.

Table 2.8: Adapted quality ratings for methodological quality of studies (adapted from ADA, 2005:27–30; ADA, 2009:42-46; CASP, 2006)

Description in words	ADA quality rating	CASP score quality rating
HIGH	(+)	$\geq 8/10$
MEDIUM	(Ø)	$\geq 5/10$ to $< 8/10$
LOW	(-)	$\geq 1/10$ to $< 5/10$

The following studies were reviewed, appraised and used in the synthesis of data.

Systematic reviews (2)

Two systematic reviews were critically appraised, and both fell in evidence class A and received quality ratings of 8/10 according to the CASP score and a (+) on the ADA quality rating system. The first systematic review was conducted on reflexology efficacy in any condition, whether acute or chronic, and the second systematic review was conducted for the research evidence base of effectiveness of reflexology in cancer care. Both systematic reviews were put on the sort list for data abstraction (Wang *et al.*, 2008; Wilkinson *et al.*, 2008). Each systematic review had a sample of five RCTs, with study methodological limitations and heterogeneity of data, but the bottom-line findings were in correlation with findings of a previously conducted systematic review that was not included because it was before 2000 (Ernst & Koder, 1997).

Narrative review (1)

Only one narrative review (Stephenson & Dalton, 2003) on the utilisation of reflexology for pain management was critically appraised. This study fell in evidence class R with a very low assessed methodology quality rating of 4/10 according to the CASP score. The quality rating with the ADA tool was negative (-), and confirmed the CASP scoring. It was excluded from the sort list after critical appraisal due to the very low methodological quality, which could have contributed to bias during the data analysis of the evidence.

Randomised controlled trials (10)

Ten RCTs were critically appraised. All were in evidence class A, but the methodology quality ratings differed. Two studies had methodology quality ratings of 8/10, three studies of 7/10, four studies of 6/10 and one study of 4/10 according to the CASP score. The quality rating according to the ADA tool was graded as (Ø) for the first nine studies. The study of Wilkinson, Prigmore and Rayner (2006), with a quality rating of 4/10, was excluded from the sort list after it was critical appraised with the ADA tool, which confirmed a negative (-) quality rating. Therefore, only nine RCTs were included in the sort list for data extraction and evidence analysis.

Experimental intervention studies (5)

Five intervention studies were appraised, and all fell in evidence class A. These studies were appraised with the RCT criteria of the CASP due to the fact that they were experimental studies that used randomised concurrent control groups, evaluate efficacy of reflexology, ensured that all subjects receive the intervention exactly the same way and

compared intervention and non-intervention outcomes. The CASP programme does not offer a separate tool for intervention studies per se, and the researcher aimed to be consistent in the critical appraisal of the experimental studies. Three studies scored a quality rating of 7/10 and two studies scored a quality rating of 6/10. The quality rating according to the ADA tool was graded as (Ø) for all five studies, therefore all five studies were included in the sort list for data extraction and evidence analysis.

Qualitative research studies (3)

The evidence-based practice movement has been characterised by its rigid view on the research methods considered to generate sound evidence, such as a narrow focus on RCTs and preferred intervention research designs. According to Dixon-Woods and Fitzpatrick (2001:125), more emphasis is presently placed on qualitative research contributions, and it is accepted that some life experiences or questions can only be answered by research studies that apply a qualitative approach. Findings produced by a qualitative research approach were previously considered as belonging to a lower hierarchy of scientific evidence compared to those of RCTs (Melnik & Fineout-Overholt, 2005:129).

Three primary studies were appraised as non-experimental or qualitative studies with the CASP checklist for qualitative research. These studies fell in evidence class D. One represented a multiple case study approach, another one a prospective audit by using a semi-structured questionnaire and the last one represented a single case report/study approach. The studies scored 8/10, 6/10 and 4/10 respectively on the qualitative checklist of CASP. The first two studies presented with a quality rating of positive (+) and neutral (Ø), respectively, on the ADA quality rating system and the last one with a quality rating of (-). The single case report study on a participant with rheumatoid arthritis was excluded after critical appraisal due to the low methodological quality (4/10 and (-)), which could have contributed to potential bias during the data analysis of the evidence. This particular study did not indicate:

- any justification for the research design;
- justification for participant selection (randomly selected from the local podiatry department);
- the researcher's role or paradigmatic perspective;
- the data-saturation point or justification for only nominal and ordinal data; or

- any description of data analysis other than rank differences displayed graphically.

Data collection was limited to two questionnaires that produced interval and ordinal data that do not enable statistical analysis. No other thematic or content analysis was performed on the data. Therefore, the researcher decided to exclude the particular study and include only the other two studies in the sort list for data extraction and evidence analysis.

2.2.1.5 Data extraction and summary

All the studies that complied with the selection criteria and that were found to be of medium to high quality after critical appraisal were included in the sort list that was used for data extraction. This was done according to two steps, namely data reduction and data display. A summary of all the relevant studies was made according to study design, time span, sample, setting, data-collection instruments, statistical analysis, intervention- versus - control, evidence class, quality rating and bottom-line finding. The summary was created in table format for the sake of display and synthesis of evidence. The summary for data extraction is displayed in Table 2.9.

Table 2.9: Data extraction of systematic reviews included for synthesis of evidence

Studies	Sample	Search	Critical appraisal method and tool
Wang, M.Y. <i>et al.</i> 2008. <i>Journal of Advanced Nursing</i> 62(5):512–520 Country: TAIWAN	RCT x 5 Total sample size 251 Study (a) n = 53 Study (b) n = 69 Study (c) n = 40 Study (d) n = 34 Study (e) n = 55	Keyterms: reflexology, foot reflexotherapy, reflexological treatment, foot massage, zone therapy Databases: Cochrane Library, PubMed, MEDLINE, EBM Reviews, ProQuestMedical Bundle, SCOPUS and Wangfane. Chinese electronic periodical services for Chinese articles Inclusion criteria: Design: Controlled clinical trials Language: English or Chinese Intervention: Reflexology as a stand-alone modality Outcomes: Including symptoms relief, psychological well-being, quality of life and patients' perceptions of reflexology Exclusion criteria: Studies evaluating a combination of reflexology with other modalities, fewer than 10 participants in each group, insufficient information on principal measures of effect or including a young age group	Project electronic search Two project members independently reviewed relevant articles for inclusion and exclusion. Originally 43 abstracts – screened titles and abstracts relevancy n = 27. Reference lists searched for additional studies Inclusion and exclusion criteria to be met – total n = 11. Total studies relevant after inclusion and exclusion criteria met n = 11. Studies excluded due to poor internal validity (6). Total studies included for systematic review: n = 5. Review done : Evidence rating system of the US Preventive Services Task Force (USPSTE) Harris <i>et al.</i> 2001
Review question and outcome	Findings, limitations and recommendations	Evidence class / quality rating	Bottom-line finding
Question: The efficacy of reflexology in any condition Outcome: There is no evidence of any specific effect of reflexology in any condition, with the exception of urinary symptoms associated with multiple sclerosis	There is no evidence of any specific effect of reflexology in any condition, with the exception of urinary symptoms associated with multiple sclerosis. It is acknowledged that the review only included papers published since 1996 and was restricted to those published in English or Chinese. Routine provision of reflexology is therefore not recommended.	A + CASP 8/10 Rigour: good. Unclear on policy/practice guidelines due to study limitations. Unclear on all important outcomes consideration due to study limitations and small sample size, which prevents statistical significance.	The efficacy of reflexology is not supported by statistical evidence from controlled clinical trials, except in one study on the efficacy for urinary symptoms associated with multiple sclerosis. Reflexology is a holistic therapy that treats the body as a whole and should be evaluated with a holistic approach. Many patients choose CAM (reflexology) as a way to empower themselves in the management of their illness/disease and therefore may not seek evidence of efficacy.

Studies	Sample	Search	Critical appraisal method and tool
Wilkinson, S. <i>et al.</i> 2008. <i>Cancer Nursing</i> 31(5):354–360 Country: UK	RCT x 5 Total sample size 220 Study (a) n = 12 Study (b) n = 17 Study (c) n = 129 Study (d) n = 26 Study (e) n = 36	Key terms: reflexology, foot massage, feet and massage, zone therapy AND cancer, neoplasm, oncology, palliative, terminal, hospice Databases: Cochrane Central Register of Controlled Trials, MEDLINE, EMBASRE, CINAHL, British Nursing Index, AMED, PsycINFO, SIGLE, Cancer LIT, Dissertation Abstracts International Inclusion criteria: Design: RCTs, controlled before and after studies and interrupted time-series studies. Adult participants with a diagnosis of cancer receiving care in any health care setting. Reflexology carried out by qualified therapist and patient-reported levels of physical and psychological indices of symptom distress and quality of life. Validated assessment tools to be used in studies. No exclusion criteria described	Project electronic search One reviewer screened titles and abstracts for relevance. Two reviewers independently screened remaining titles and abstracts for inclusion in review. Two to four reviewers independently reviewed the full texts of potentially eligible studies for inclusion in review. Originally 387 studies from searches. Duplicates identified x 75 and excluded to leave studies n = 311. Appraisal done and excluded a further 306 studies. Final studies left for systematic review: n = 5. Tool for review: Checklists of Juni <i>et al.</i> (2001) and Jadad <i>et al.</i> (1996).
Review question and outcome	Findings, limitations and recommendations	Evidence class / quality rating	Bottom-line finding
Question: To assess the evidence of reflexology in improving physical and psychological well-being in patients with cancer Outcome: No definitive conclusions can be drawn due to methodological limitations of the included studies – more studies of methodological high quality are needed in this area	No firm conclusions can be drawn on effectiveness of reflexology for the relief of cancer treatment symptoms and co-morbidities, due to paucity of data. Available evidence is limited, due to methodological limitations of studies and no long-term follow-up. None of the studies investigate the cost-effectiveness of reflexology or foot massage by nursing staff. Suggestion: Reflexology may confer benefits to people with cancer over those offered by a foot massage or no-intervention control. Important questions rose about non-specific effects common to all practitioner-based complementary therapies, the active ingredient of reflexology and the cost-effectiveness of the use of trained reflexologists.	A + CASP 8/10 Rigour: good. Unclear on policy/practice guidelines. Unclear on all important outcomes consideration due to paucity and heterogeneity of data and methodology limitations of studies such as small sample sizes.	The efficacy of reflexology is not supported by evidence from controlled clinical trials in patients with cancer. Studies have methodological limitations. Studies investigated various physical symptoms and markers of psychological well-being of cancer patients and not the effect of reflexology on the person as an entity. Reflexology claims to treat the body as a whole in order to rebalance. Reflexology can be taught to cancer patients' partners or carers to improve quality of life and enhance personal and carer relationships.

Table 2.10 **Data extraction of experimental studies included for synthesis of evidence**

Author and journal details	Year/ country	Sample		Data instruments	Design	Statistics	Intervention and control	Attrition %	Intention to treat	Evidence class quality rating	Limitations	Bottom-line finding
Dalal, K., Tripathi, M., Bajpaj, V., Saraswat, D. & Singh, A. <i>Epilepsia</i> 49(Suppl. 7): 182	2008 New Delhi, India	45	Epilepsy Epilepsy clinic Convenience	Seizure frequency Quality of life in epilepsy (QOLIE) 31	Patient-blind RCT	Standard deviation range $p = 0.0001$. Wilcoxon rank sum test.	Reflexology and drug therapy versus drug therapy alone	-	-	A Ø CASP 7/10	Small sample size	Statistically significant reduction in the frequency of seizures in reflexology and conventional therapy group. Control group received only conventional therapy. Reflexology suggests a promising role in the management of epilepsy.
Quinn, F., Hughes, C.M. & Baxter, G.D. <i>Complementary Therapies in Medicine</i> 16:3-8	2008 UK	15 Power calculation $n = 74$ Staff (reflection general population)	Chronic lower back pain (CLBP) University of Ulster Convenience	VAS – pain Roland-Morris McGill – pain SF-36 (Ware & Sherbourne, 1992)	Double blind RCT	MEDIAN inter-quartile values	Reflexology , simple foot massage, excluding spine reflex on feet	0%	No	A Ø CASP 7/10	Small sample size. Inexplicit categorisation of diagnosis/prognosis of CLBP. No other medical condition recorded.	Reflexology appears to offer promise as a treatment in the management of low back pain. Reflexology group showed important clinical reduction in low back pain in VAS & SF-36.
Poole, H., Glenn, S. & Murphy, P. <i>European Journal of Pain</i> 11:878-887	2007 UK	243 Power calculation $n = 240$	CLBP General practitioner surgeries, local health centre Convenience	SF-36 (Ware & Sherbourne, 1992) ODQ BDI – II VAS – pain	RCT	Adjusting pre-treatment scores. Repeated measures. ANCOVA.	Three groups. Reflexology. Progressive muscle relaxation. Non-intervention or usual care.	34%	Yes	A Ø CASP 7/10	High attrition. Inexplicit categorisation of diagnosis/prognosis of CLBP. Outcome measures not sensitive enough. Additional CAM while in study.	Reflexology for CLBP cannot be recommended or its widespread use and funding within the National Health System. Reflexology appears to be safe therapy.
Siev-Ner, I., Gamus, D., Lerner Geva, L. & Achiron, A. <i>Multiple Sclerosis</i> 9(part 4):356-361	2003 Israel	71 Power calculation $n = 70$	MS Multiple sclerosis hospital clinic Convenience	VAS – intensity paresthesias Urinary symptoms American Urological Association (AUA) symptom score Muscle strength Ashworth score	Double blind RCT	$\alpha = 0.05$ P values Mean standard deviation Wilcoxon rank sum test Mann-Whitney U-test SPSS-PC Version 8.0	Reflexology Calf area massage	-	Yes	A Ø CASP 7/10	Attrition not reported	Reflexology positively affected muscle strength and tonus and reduced sensory and urinary symptoms. Reflexology is a safe treatment. $P = 0.06$ muscle strength, Paresthesia $p = 0.04$

Author and journal details	Year/country	Sample		Data instruments	Design	Statistics	Intervention and control	Attrition %	Intention to treat	Evidence class quality rating	Limitations	Bottom-line finding
Tovey, P. <i>British Journal of General Practice</i> 52(474):19–23	2002 UK	34 Power calculation n = 36	Irritable bowel syndrome (IBS) Primary care settings, surgeries Convenience	Abdominal pain Constipation/diarrhoea Bloating Health assessment sheet used in other IBS trials Daily assessment on five-point scale (0–4)	Single blind RCT	MEDIAN inter quartile range (IQR) 5% significance to detect difference between groups	Reflexology – exclude lifestyle advice. Non-reflexology foot massage	18%	No	A Ø CASP 6/10	Sample ethnically homogeneous. “Hard to treat” group. Inexplicit categorisation of diagnosis/prognosis of IBS.	No evidence that reflexology had any benefit for patients with IBS. Reflexology appears un-researched.
Williamson, J., White, A., Hart, A. & Ernst, E. <i>An International Journal of Obstetrics and Gynaecology</i> BJOG 109:1050–1055	2002 UK	76 Power calculation n = 80	Menopausal symptoms School of Complementary and Alternative Health Convenience	WHQ – well-being WHQ – symptoms MP VAS – hot flushes + night sweats MYMOP – quality of life	Patient-blinded RCT	MEDIAN confidence interval (CI) 95% ANCOVA	Reflexology – exclude lifestyle advice. Non-specific foot massage.	21%	Yes	A Ø CASP 8/10	Small sample size. Placebo effect underestimated. Handling of MYMOP – un-supervised. Short duration of follow-up. Blinding unsuccessful.	Reflexology was not shown to be more effective than non-specific foot massage in the treatment of psychological symptoms of menopause. Improvements were encountered in both groups – may have been due to non-specific effects.
Kulik, D. MA thesis, Place, University of the Pacific	2002 Sacramento, USA	29	Type II diabetic neuropathy Convenience	Neuropathic Pain Scale (NPS) Short-form McGill Pain Questionnaire (SF-MPQ) Multidimensional Pain Inventory (MPI) Profile of Mood States (POMS) VAS – pain Dermatorm temperature strips foot temperature	Randomised split-plot factorial design	$\alpha = 0.05$ ANOVA paired sample t-tests two-sided	Three groups. Reflexology. Effleurage massage. Waiting list.	30%	-	A Ø CASP 7/10	Small sample size; split-plot factorial design need very large sample. Inexplicit categorisation of diagnosis/prognosis of diabetic neuropathy. More rigorous research needed in this area to make informed decisions on accessibility and provisioning of CAM in the health care of diabetics	Reflexology has no superior effects over effleurage massage, but both groups improved on pain of neuropathy in relation to no improvement in waiting-list group.
Brygge, T., Heinig, J.H., Collins, P., Ronborg, S., Gehrchen, P.M., Hilden, J., Heegaard, S. & Poulsen, L.K. <i>Respiratory Medicine</i> 95:173–179	2001 Denmark	40	Asthma Allergy unit Convenience	Diary cards Lung function tests: Peak flow registrations Bronchial histamine challenge test SF-36 – quality of life	Double-blind RCT Placebo-controlled	Tests with two-sided p values < 5% reported significant MEDIAN symptom scores	Reflexology. Simulated reflexology using placebo areas.	-	-	A Ø CASP 6/10	Small sample size. Not sufficient compliance due to interrupted interventions as objected by reflexologist. Analysis was performed to overcome this, with no significant differences in outcome.	No significant statistical evidence that reflexology has a specific effect on asthma beyond placebo effect.

Author and journal details	Year/ country	Sample		Data instruments	Design	Statistics	Intervention and control	Attrition %	Intention to treat	Evidence class quality rating	Limitations	Bottom-line finding
Hodgson, H. <i>Nursing Standard</i> 14(31):33–38	2000 Scotland	12	Cancer with various tumour types NHS District General Hospital Convenience	VAS – quality of life Holmes & Dickerson 1987	Double-blind RCT	P values MEAN Mann-Whitney U-test Descriptive statistics	Reflexology Gentle foot massage	-	-	A Ø CASP 6/10	Small sample size. No consideration for conventional therapy of patients e.g. laxatives. Inexplicit categorisation of diagnosis/prognosis of cancer. Researcher not blind to patients' intervention and not all components of quality-of-life scale were used.	Reflexology does have an impact on the quality of life of patients in the palliative stage of cancer. Suggests that provisioning of reflexology in general setting for palliative care could be beneficial to promote quality of life of patients.
Hodgson, N.A. & Andersen, S. <i>The Journal of Alternative and Complementary Medicine</i> 14(3):269–275	2008 Philadelphia	21	Mild to moderate stage dementia Nursing home Convenience	salivary alpha amylase (sAA) – stress AARS – depression, anxiety, anger, pleasure and interest CNPI behavioural scale for non-verbal older adults with cognitive impairment – pain Folstein's MMSE – cognitive assessment	Experimental, randomised cross-over design. Data collectors blind to group conditions	STATA version 9.0 Repeated measures analysis ANOVA Between subject effect and within subject effect with p values	Reflexology versus friendly visits	9%	Yes	A Ø 6/10 CASP	Small sample size with homogeneous structure of race and culture. Inexplicit categorisation of diagnosis/prognosis of dementia. Sample not randomly selected from nursing home residents.	Residents with mild to moderate stage dementia had clinically and significantly reductions in pain and anxiety after receiving reflexology treatments.
Stephenson, N.L., Swanson, M., Dalton, J., Keefe, F.J. & Engelke, M. <i>Oncology Nursing Forum</i> 34(1):127–132	2007 USA	86	Metastatic cancer Hospital setting Convenience	Brief Pain Inventory (BPI) – pain SF-MPQ (Melzack, 1987) – pain VAS – (Cline <i>et al.</i> , 1992) – anxiety	Experimental pre-/post-test with randomisation to experimental and control groups	SPSS version 13 T-tests and chi-square tests one-way between groups analysis of covariance Effect size eta-squared statistic Statistical significance $p \leq 0.05$	100	High, therefore drop longitudinal study	-	A Ø 7/10 CASP	Primary author provided reflexology instruction and administered the pain and anxiety scales. Inexplicit categorisation of diagnosis/prognosis of metastatic cancer. More research with repetitive sessions reflexology – investigate cumulative effects	Reflexology can be used to decrease anxiety statistically significantly and pain clinically in patients with metastatic cancer.

Author and journal details	Year/ country	Sample		Data instruments	Design	Statistics	Intervention and control	Attrition %	Intention to treat	Evidence class quality rating	Limitations	Bottom-line finding
Quattrin R. <i>et al.</i> <i>Journal of Nursing Management</i> 14(2):96–105	2006 Italy	30	Hospitalised cancer patients in chemotherapy in oncology unit Convenience	Spielberger State-Trait Anxiety Inventory (STAI) – self-reported anxiety	Experimental pre-/post-test comparative group design. Assigned to groups in accordance with criteria.	Standard deviation P values T-tests	-	-		A Ø 6/10	Small sample size. Only short-term effects. No categorisation by diagnosis or metastasis extensions. Preferable to use two different nurses to administer intervention and collect data.	Reflexology significantly decreases anxiety in patients undergoing second and third cycles of chemotherapy. Study encourages reflexology in nursing practice with cancer patients, but nurse must be qualified expert in reflexology to educate families to practice this simple skill cost-effectively at home.
Stephenson, N., Dalton, J. & Carlson, J. <i>Applied Nursing Research</i> 16(4):284–286	2003 USA	36	Metastatic cancer regional hospital Convenience	Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) 2001 – self-reported pain scale	Experimental repeated measures design with a stratified random sample	Statistical – ANOVA of baseline-adjusted post-treatment measures Significance with $p < 0.01$	Reflexology versus control of no intervention	-		A Ø 7/10	Small sample size. Inexplicit categorisation of diagnosis/prognosis of metastatic cancer.	Reflexology suggests an immediate positive effect for patients with metastatic cancer, but no long-term effects. No statistical significance.
Stephenson <i>et al.</i> <i>Oncology Nursing Forum</i> 27(1):67–72	2000 USA	23	Breast and lung cancer medical/ oncology unit Convenience	VAS – anxiety (Cline <i>et al.</i> , 1992) SF-MPQ – pain (Melzack, 1987)	Quasi-experimental, pre-/post-, cross-over trial	Statistical analysis descriptive statistics, correlations and univariate analysis. Wilcoxon and signed-rank test for highly skewed distribution.	Reflexology versus control of no intervention	-		A Ø 7/10	Small sample size. Unusually high representation of males with lung cancer. Two types of cancer with metastasis.	Reflexology can be used to decrease anxiety statistically significantly and pain clinically in patients with cancer. More research with repetitive sessions reflexology – investigate cumulative effects.

Table 2.11 Data extraction of non-experimental studies included for synthesis of evidence

Author and journal details	Year/ country	Sample	Design / Rigour	Ethics	Intervention / control	Data instruments / collection	Data analysis	Attrition	Evidence class quality rating	Limitations	Bottom-line finding
Gunnarsdottir, T.J. PhD dissertation, Place, University of Minnesota	2007 Iceland	Six case studies. Purposively selected and recruited with the assistance of a medical specialist. Physician specialised in treating patients with fibromyalgia syndrome. Inclusion criteria determined to include only adults with the symptoms of fibromyalgia syndrome and exclude other diseases or symptoms. Purposive sampling	Qualitative multiple case study approach consistent with whole-systems research to explore the nature of reflexology as a therapy and its effectiveness as a treatment for women with fibromyalgia syndrome. – prolonged engagement in field, member checking, structural coherence and reflexivity by field notes.	Informed consent of participants. May withdraw at any point of study. Anonymity and confidentiality by unique ID codes and newly given names. Ethical approval from Institutional Review Board and the National Bioethics Committee.	Thoroughly describe. Duration 45 minutes per session or more and ten treatments per case. No control – not applicable	Transcribed tape-recorded interviews. Daily diary on sleep, pain, medication intake and “other” comments. Observation field notes. Picture diagram of body indicate pain areas and score pain intensity on Numerical Rating Scale (NRS) from 0 (no pain at all) to 10 (worst pain imaginable). Dense descriptions, content analysis and literature control for dependability.	With-in case analysis – coding and thematic content analysis of individual cases in case reports. Cross-case analysis commonalities, contradictions, confusions, uniqueness and missing information coded, clustered, reflected and reread for assertions on evidence of findings. Dense description of methodology and content analysis process for confirmability and dependability	Not applicable	D + 8/10 CASP	Study contains subjective information from the six participants and the reflexologist – limiting the transferability to other populations.	Reflexology may be beneficial to nursing and health care practice, as the study found that reflexology shows emotional and spiritual healing effects on the body in relieving the symptoms of fibromyalgia syndrome by reduction in pain and increase in overall well-being.
Gambles, M., Crooke, M. & Wilkinson, S. <i>European Journal of Oncology Nursing</i> 6(1):37–44	2002 UK	46 questionnaires, 34 returned. Convenience sample Outpatients of palliative care setting in North of England with cancer diagnosis.	Qualitative exploration Of patients' perceptions with semi-structured questionnaire. Attrition rate 26%.	Informed consent of participants. May withdraw at any point of study. Anonymity.	Brief description. Course four to six treatments. Duration: tailored to meet patients' holistic needs. No control – not applicable	Semi-structured questionnaire with open and close-ended questions on perceptions.	Thematic analysis. Clear description of all themes and conclusions.	Attrition 26%	D Ø 6/10 CASP	Not rigorous assessment of reflexology's effectiveness, therefore not able to generalise to other settings.	Reflexology could be beneficial in physical, psychological and spiritual terms for patients receiving palliative care in terms of personal relaxation, coping strategies, therapeutic relationships and establishment of therapeutic environment.

2.2.1.6 *Critical synthesis of findings*

After the data-extraction procedure was concluded and studies had been summarised, the data was critically synthesised by closely examining the variables of interest to identify patterns, similarities, differences, conflicting evidence and relationships in relation to the review question. The review question entailed critically appraising, analysing and synthesising available evidence of the utilisation of reflexology in adults with chronic disease to enhance vitality and well-being to promote quality of life. Viewed in the light of the heterogeneous samples, settings and designs, an integrative literature review was considered more applicable to answer the review question. The identified variables and findings will now be discussed.

2.2.1.6.1. Time span and origin

The time span for the review was from January 2000 to December 2008. The sort list of included studies for evidence analysis contained 18 studies. Nine studies were conducted from 2000 until 2003 and nine studies from 2006 until 2008. It appears that there was a notable scarcity of studies on the utilisation of reflexology in adults with chronic disease from 2004 to 2005.

Non-experimental studies of good quality on the utilisation of reflexology in adults with chronic disease appear to be very scarce. One study from the UK in 2002 and a more recent study in 2007 in Iceland were included for evidence analysis after review and appraisal.

Two Western countries that were actively involved in experimental research on reflexology from as early as 2000 were the UK and the USA. Most of the studies in the evidence inclusion report are from these two countries.

A good-quality systematic review was done in Taiwan during 2008 in accordance to five specific steps to conduct a systematic review as prescribed by Khan, Kunz, Kleijnen and Antes (2003:118). The systematic review was on the effectiveness of reflexology in any condition, and it was very interesting to note that the included studies for the systematic review were from the UK, Israel and Denmark and none of the eastern countries were presented. The outcome was consistent with the findings of current research in the Western world during the given time span.

2.2.1.6.2 Samples and settings

Eight of the fourteen experimental studies presented with relative small sample sizes and no indication of power calculation performed before conducting the particular studies. Inappropriate sample sizes place limitations on the results of the experimental studies in various ways, such as leading to insignificant statistical results, no generalisation to the wider population and the drawing of indefinite conclusions (Burns & Grove, 2005:354-355). Ten experimental studies presented with a sample size smaller than 50 subjects; three experimental studies presented with a sample size larger than 50 subjects, but smaller than 100 subjects; and only one study presented with a reasonable sample size of 243 subjects. Therefore most of the studies present with statistical insignificant results, although clinical differences in measurements between groups were present.

Convenience sampling methods were followed in all experimental studies, especially in hospital settings; therefore, the samples were not well representative of the general population with the various chronic diseases. This limited the generalisation of findings to other populations with the same chronic disease and negatively influenced the quality rating of studies. Randomisation of samples to intervention and control groups was done in most cases to control for non-specific factors.

The samples of experimental studies were on chronic diseases of various typologies and therefore not based on a homogenous population, although the studies were reviewed under the umbrella of chronic disease. Five studies represented cancer, palliative care and related cancer metastasis, two studies represented chronic low back pain and the others were conducted on menopausal symptoms, irritable bowel syndrome, diabetic neuropathy, epilepsy, asthma, dementia and fibromyalgia syndrome.

Experimental studies were mostly undertaken in the hospital care setting, tertiary care / palliative setting or primary care settings, therefore longitudinal designs were very difficult to apply due to unpredictable lengths of hospital stay. The few longitudinal studies that were conducted had high attrition rates, which placed a further limitation on the methodological quality rating of the study.

Non-experimental studies presented overall with reasonable sample sizes to complement the data-saturation points and used non-probability sampling methods to enhance the transferability and confirmability of the studies. The samples and settings were heterogeneous, one on women with fibromyalgia syndrome purposively selected from the

community and the other a convenience sample of patients with cancer diagnosis from an outpatient palliative clinic.

The heterogeneity of the samples and settings contributed to complexity of data analysis, but applicable variables were identified to comply with the variables of the experimental studies.

2.2.1.6.3 Data-collection instruments used in the studies

All the instruments used in the experimental studies were described as validated for reliability and validity. Commonalities of data-collection instruments used were noted in a few experimental studies. The Short-Form 36 for quality of life (Ware & Sherbourne, 1992) was used by both studies on chronic low back pain. It is a generic self-report measure to provide an assessment on eight dimensions of quality of life that are health-related, namely

- physical functioning;
- social functioning;
- role limitations due to physical problems;
- role limitations due to emotional problems;
- mental health;
- energy and vitality;
- pain and
- general perception of health.

The dimensions were therefore in line with the current review question, which addressed vitality, and well-being to promote quality of life.

The experimental studies conducted on cancer, metastasis and related diagnosis of cancer used several data-collection instruments. The Visual Analogue Scale (Cline *et al.*, 1992) was used in two studies to measure anxiety and the SF-MPQ (Melsack, 1987) was used in three studies to measure pain and quality of life. Data-collection instruments for anxiety and pain in the cancer population appeared to be consistent, appropriate and valid to answer the review question.

Hodgson (2000) used a modified Visual Analogue Scale (Holmes & Dickerson, 1987) to measure quality of life in a cancer population, but during the actual study observed that five of the twenty-eight components in original tool had been omitted due to a typing error. The study was nevertheless continued, although the researcher acknowledged it as a threat and limitation to the validity and reliability of the study. This incident leads to a neutral quality rating of the study, which negatively influenced the evidence grading.

The data-collection instruments used in the non-experimental studies were appropriate to the study designs and complemented it. The data in the study on fibromyalgia syndrome were dense, with various perspectives and more than one resource, therefore it answered well to trustworthiness by means of credibility, transferability, dependability and confirmability. The study on cancer patients' perceptions of reflexology used an open-ended questionnaire to obtain more intense and individualised responses from the participants in order to be trustworthy.

2.2.1.6.4 Data analysis of studies

All the experimental studies that have been included for evidence analysis used statistical analysis to draw conclusions. The statistics that were mostly used were the mean, median, inter-quartile range, standard deviation and covariance analysis. T-tests, ANOVA, ANCOVA, Wilcoxon rank sum tests, the Mann-Whitney U-test and chi-square tests to detect variance between experimental and control groups were furthermore used.

Tests for statistical significance that were used include p values of $p = 0.05$ and $p = 0.01$ with confidence intervals, which showed that results were not due to chances higher than 1 to 5%. The T-test (parametric analysis technique) was used to determine significant differences between measures of dependent and independent groups.

The ANCOVA was mostly used to detect variance between the intervention and control group and to adjust for confounding variables. One study that used more than two groups used the ANOVA appropriately to compare variance between groups to the variability within the groups (Burns & Grove, 2005:727–755).

There was no statistically significant effectiveness of reflexology, except in two studies that showed statistically significant improvement on sensory and urinary symptoms associated with multiple sclerosis (Siev-Ner *et al.*, 2003) and a significant reduction in anxiety of patients with breast and lung cancer (Stephenson *et al.*, 2000). Clinical differences between experimental and control groups did indeed exist on the reduction of

pain, anxiety and well-being, but when statistical analysis for significance ($p = 0.05$) was introduced it produced insignificant or borderline results. Most of the studies used small sample sizes, which hampered the statistical analysis.

Non-experimental studies used thematic analysis, with-in case analysis, cross-case analysis, coding, reflection and synthesis to draw conclusions. Data were complex, dense and submitted to member-checking. All data-analysis procedures were described in detail in both studies. Data analysis themes were displayed and quotes were given of appropriate themes.

2.2.1.6.5 Intervention versus control strategy

All of the experimental studies had intervention and comparison groups; two studies used the cross-over design with at least a 24-hour or more wash-out period to eliminate accumulative effects.

The non-experimental studies did not use comparison groups, as it was not appropriate to the research design.

Reflexology was performed in a standardised way according to the principles of Fitzgerald, Ingham, Dougans, Marquardt or Crane in both experimental and non-experimental studies. Stimulation of specific reflex/zone points on the body and feet of participants were carried out by specialised finger-pressure techniques and effleurage massage strokes by the therapist.

Most of the studies conducted between the years 2000 and 2003 used simple foot massage or non-specific foot massage as control to the intervention of reflexology to limit confounding factors. None of these studies report statistical significant results.

Several studies with small sample sizes reported by Stephenson and colleagues, report no intervention as control or more recently report a reading session as control (Stephenson *et al.*, 2000; Stephenson *et al.*, 2003 and Stephenson *et al.*, 2007). It is interesting to note that no statistical significance was reported in the data analysis of these studies, although Stephenson and colleagues concluded that significant clinical reductions in pain and anxiety of patients with diagnoses of lung cancer and metastatic cancer had been noted (Stephenson *et al.*, 2000; Stephenson *et al.*, 2003 and Stephenson *et al.*, 2007).

A study conducted in Israel, with a sample size of 71 participants, used non-specific calf massage as control to reflexology as intervention and report statistically significant results

in terms of improvement in sensory and urinary symptoms associated with multiple sclerosis (Siev-Ner *et al.*, 2003).

2.2.1.6.6 Designs, quality rating and evidence class of studies

Quality rating of studies was done according to the appropriate tools of CASP (2006) and that of the American Dietetic Association evidence analysis manual (ADA, 2005). The CASP numerical scores were used together with the ADA criteria of positive (+), neutral (Ø) or negative (-) to grade the methodological quality. The adapted and merged quality-rating system was displayed in Table 2.8.

Two systematic reviews of positive (+) quality rating that fell in evidence class A were included in the evidence analysis to compare the current review findings on primary studies in this study to recent research reviews of primary studies. A review of the methodological quality of experimental studies conducted in the time frame 2000 to 2003 indicated considerable commonalities in methodological limitations such as small sample sizes, non-probability samples, unsuccessful blinding of participants, no blinding of outcome assessors and inexplicit categorisation of diagnosis/prognosis of the typology of involved chronic disease.

The methodological quality of experimental studies conducted in the time frame 2006 to 2008 was more in line with rigorous research designs. Inadequate sample size was still a problem, but limited by cross-over designs. Blinding of participants and outcome assessors were consistently applied together with the implementation of longitudinal designs. Inexplicit categorisation of diagnosis/prognosis of the typology of the involved chronic disease was still not successfully attended to. These findings were consistent with the findings of the included systematic reviews.

All the primary experimental studies in this study had a quality rating of neutral (Ø). The RCTs were in evidence class A and the five experimental before and after studies with comparison groups in evidence class A. They were all included to review the evidence of effective utilisation of reflexology in chronic disease. The evidence analysis was limited to mostly neutral quality ratings of the study methodology and therefore had a negative influence on the grading of evidence in the conclusion statement (ADA, 2005:42–45).

The non-experimental studies of evidence class D presented with different quality ratings. The study that explored cancer patients' perceptions of reflexology with a semi-structured

questionnaire had a neutral (Ø) quality rating. The study on the exploration and nature of reflexology in the treatment of adult women with fibromyalgia syndrome had a positive (+) quality rating. This study provides important insight into reflexology as a holistic treatment modality to enhance physical vitality and psychosocial well-being in women with fibromyalgia syndrome. The difference in the quality ratings of the two non-experimental studies had a negative influence on the grading of evidence in the conclusion statement (ADA, 2005:42–45; ADA, 2009:63).

2.2.1.6.7 Bottom-line findings

The bottom-line findings will now be discussed according to the chronic disease condition that it represents. Bottom-line findings were consistent for the various diseases.

Intractable epilepsy

Reflexology treatment has shown significant statistical reduction in the frequency of seizures of patients with intractable epilepsy. This was reported by an RCT that falls in evidence class A (Dalal et al., 2008).

Multiple sclerosis:

There is significant statistical evidence of class A of the effectiveness of reflexology to enhance vitality and well-being in adults with multiple sclerosis to promote quality of life, as shown by the improvement of sensory and urinary symptoms associated with this disease. This was a common bottom-line finding in a systematic review (Wang *et al.*, 2008) and a primary experimental study of class A evidence (Siev-Ner *et al.*, 2003).

Cancer:

There is no significant statistical evidence of class A on the efficacy of reflexology with cancer patients as reported by the systematic review (Wilkinson et al., 2008).

However, there is significant statistical evidence of class A that supports the utilisation of reflexology to decrease *anxiety* in patients with breast and lung cancer (Stephenson *et al.*, 2000). Several other studies conducted on anxiety in cancer patient populations report a significant statistical decrease in anxiety after reflexology treatments (Hodgson & Andersen, 2008; Quattrin *et al.*, 2006; Stephenson *et al.*, 2007).

One study conducted on patients in the palliative stage of cancer who received reflexology treatments report statistically significant improvements in pain, constipation, sleep, anorexia and nausea (Hodgson, 2000). This study was an RCT and also in evidence class

A. Other interventional experimental studies conducted on the reduction of *pain* in cancer patient populations report insignificant statistical reduction of pain as result or borderline significant statistical results in relation to the reduction of metastatic cancer pain (Stephenson *et al.*, 2000; Stephenson *et al.*, 2003; Stephenson *et al.*, 2007). All of these studies were of evidence class A.

A non-experimental study in evidence class D reports the following perceptions of patients in cancer palliative care after a course of reflexology treatments:

- relaxation;
- relief from tension and anxiety;
- feelings of comfort; and
- improved well-being (Gambles *et al.*, 2002).

This finding is consistent with the findings of experimental studies on the reduction of anxiety and pain in cancer populations.

Diabetic neuropathy

Reflexology has no significant statistical superior effects over effleurage massage in the improvement of pain in diabetic neuropathy, but both interventions clinically improve the pain of diabetic neuropathy. This was reported by a randomised split-plot factorial design and falls in evidence class A (Kulik, 2002).

Fibromyalgia syndrome

Reflexology embodies emotional and spiritual healing effects on the body in relieving the symptoms of fibromyalgia syndrome in women by reducing pain and increasing overall well-being. This was reported by a non-experimental case study in evidence class D (Gunnarsdottir, 2007). This finding is consistent with the findings of experimental studies on the reduction of anxiety and pain in cancer populations.

The above mentioned chronic diseases all showed significant statistical or clinical benefit after reflexology treatments while the following chronic disease showed no significant statistical evidence or clinical benefit after reflexology treatments.

Chronic low back pain

There is no significant statistical evidence (class A) that reflexology is effective to improve chronic low back pain (CLBP) (Poole *et al.*, 2007; Quinn *et al.*, 2008).

Irritable bowel syndrome

There is no significant statistical evidence (class A) that reflexology has any benefit for patients with Irritable Bowel Syndrome (IBS) regarding bloatedness, abdominal pain and constipation/diarrhoea (Tovey, 2002).

Menopausal symptoms

There is no significant statistical evidence (class A) that reflexology has been more effective than non-specific foot massage in the treatment of physical and psychological symptoms of menopause. Improvements were encountered in both groups in one study, which may have been due to non-specific factors (Williamson *et al.*, 2002).

Asthma

There is no significant statistical evidence (class A) that reflexology has a specific effect on asthma beyond the placebo effect (Brygge *et al.*, 2001).

2.3 CONTEXTUALISING FINDINGS TO THE SOUTH AFRICAN CONTEXT

The contextualisation of findings requires that generalisation of the findings of a study are truly representative of the target population (Burns & Grove, 2005:342). The South African context itself differs from the studied context of the included primary studies of the current review, as to the various typologies of chronic diseases that have been explored. Stroke, cardiovascular diseases, Diabetes Mellitus and AIDS-related diseases are currently more prevalent in South Africa than multiple sclerosis, fibromyalgia syndrome or irritable bowel syndrome, although it is part of the overall scope of health care in South Africa. The five most prevalent chronic diseases in South Africa are HIV/AIDS, Ischaemic heart disease, Stroke, Tuberculosis and interpersonal violence (Norman *et al.*, 2006:12).

If one relates this to the bottom-line findings of this study there seems to be no direct relation. The target population in the included studies of the review was adults with chronic diseases, such as multiple sclerosis, various cancer typologies, chronic low back pain, irritable bowel syndrome, fibromyalgia syndrome, asthma, intractable epilepsy,

diabetic neuropathy and menopausal symptoms. However although the included primary studies for evidence analysis produced a heterogeneous sample frame with inexplicit categorisation of the various typologies of chronic diseases some of the specific symptoms like pain, anxiety, feelings of discomfort and decreased well-being can be contextualised to the South African context due to the similarity of symptomatic patterns that the various chronic diseases have in common.

The bottom-line findings were consistent across most of the primary studies with a difference in outcome regarding three detached experimental primary studies on chronic diseases such as irritable bowel syndrome, menopausal symptoms and asthma. The conflicting evidence regarding the benefit of reflexology in irritable bowel syndrome, menopausal symptoms and asthma have been disclosed in three detached experimental studies with neutral quality ratings and a different chronic disease as subject in each case without validations made in further studies. Some of the outcomes were intermediate outcomes to the current review question as demonstrated through symptoms of bloatedness, abdominal pain, changes in patterns of diarrhoea/constipation, hot flushes, night sweats, lung function measurements and bronchial histamine challenge tests. Chronic disease is a collective name for a wide scope of different diseases that were chronic in nature and share the common ground of impaired physical vitality, subjective feelings of un-wellness and deficits in quality of life. The bottom line findings and review question was therefore in correlation with chronic disease as collective noun although it consisted of different diseases per se. Therefore the conflicting evidence is handled with caution and further studies should be conducted to verify these outcomes.

The findings of this study should therefore be used with caution. Many of the specific findings may be translated to the South African context but have to be validated in future research.

2.4 CONCLUSION

Seven variables emerged from the data analysis: time span and origin; sample and settings; data-collection instruments used; data analysis used; intervention versus control strategy; designs, evidence class and quality rating; and bottom-line finding. The author draws the conclusion statement from the findings of these variables and in relation to answering the review question appropriately.

What evidence exists on the utilisation of reflexology as CAM modality in adults with chronic disease to improve well-being and quality of life?

There is fair evidence that reflexology as CAM modality improves well-being and quality of life in adults with chronic disease as demonstrated through statistical significant reduction in intractable epileptic seizures, improved sensory and urinary symptoms associated with multiple sclerosis, a clinical significant decrease in anxiety associated with cancer patients during palliative care, improved relaxation, coping and well-being in cancer patients during palliative care; and reduction in pain together with improvement in overall well-being in patients with fibromyalgia syndrome.

The strength of the evidence is considered fair according to the adapted evidence grading system of the ADA Evidence analysis manual (ADA, 2005; ADA 2009:63).

2.5 RECOMMENDATIONS

The findings of the review enables recommendations to be made for nursing practice, nursing education and nursing research on the utilisation of reflexology as CAM modality for adults with chronic disease to improve well-being and quality of life.

2.5.1 Nursing practice

Reflexology as a CAM modality may be incorporated into nursing practice to make it more accessible to patients with chronic disease or disabilities or those undergoing palliative care to promote well-being and quality of life.

2.5.2 Nursing education

Reflexology as a CAM modality can be included in the nursing curriculum to inform, educate and equip nurses with speciality skills in community care, palliative care, caring for the aged and rehabilitation care to promote well-being and quality of life in patients with chronic diseases.

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2.5.3 Nursing research

Future research with appropriate design and a holistic approach to confirm and validate the findings is recommended to enrich the existing knowledge base of nursing and to render

more individualised patient care that is holistic in nature to promote well-being and quality of life in patients with chronic diseases.

2.6 LIMITATIONS

The integrative literature review was conducted on studies presenting mostly with a neutral quality rating and a mix of class A, C and D evidence; therefore, generalisation is limited to the specific context and cannot be generalised to the wider population or context.

2.7 FINAL CONCLUSION

Given the variations in chronic diseases, typology and context the evidence that reflexology as CAM modality benefit patients with chronic disease to promote well-being and quality of life are fair. However more integrative and high quality research are needed to verify and validated the findings of this study in the South African context.

Reflexology appears to be a non-invasive therapy with no reported adverse effects that may enhance vitality and well-being in adults with chronic disease to promote their quality of life. Reflexology is a holistic CAM modality that treats the patient as individual in a unique way to balance underlying energy imbalances and synchronise the body to its own emotional and spiritual healing mechanism to actively pursue wholeness/integrity on physical, psychological and social level. Patients should be informed of the possible benefits and left to decide for themselves if they want to utilise it as part of emotional and spiritual healing to empower themselves in their pursuit towards wholeness/integrity.

Nurses should be educated on reflexology as CAM modality to react informative on patients inquiries and to utilise it as part of community and palliative care in conventional health care practice. Reflexologists and nurses trained in reflexology practice can teach care-givers to utilise reflexology in community and palliative care to promote well-being and quality of life.

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CHAPTER 3

CONCLUSIONS, RECOMMENDATIONS AND LIMITATIONS OF STUDY

3.1 INTRODUCTION

This integrative literature review critically reviewed identified experimental and non-experimental studies for method and quality, systematically analysed and synthesised the findings of good quality studies to appropriately answer the review question. The findings of this integrative literature review consisted of seven variables of interest that emerged during the data extraction and analysis of the review evidence of the utilisation of reflexology as CAM modality to enhance vitality and well-being in adults with chronic disease to promote quality of life.

The seven variables that emerged from the data analysis were: time span and origin; sample and settings; data-collection instruments; data analysis; intervention versus control strategy; designs, evidence class and quality rating; and bottom-line finding. These variables were closely examined to identify patterns, similarities, differences and conflicting evidence to explore possible relationships in relation to the review question and strength of evidence grading as seen in table 3.1.

3.2 CONCLUSIONS

The main patterns that emerged from the variables are now described briefly. The active participation of western countries to conduct good quality research of the utilisation of reflexology in adults with chronic disease is notable. An overall heterogeneity was displayed in samples, settings and chronic diseases during the data extraction of the primary studies included for evidence analysis.

Most of the data collection instruments that were used in the primary studies of the current review were all validated and tested for reliability and utilised in previous research studies.

All of the primary studies made use of non-probability sampling method by selecting a purposive sample; the sample sizes of the experimental studies were relative small and therefore lead to limitations during statistical analysis. Non-

probability sampling method was followed in the non-experimental primary studies that complement the design and was appropriate to the research design.

Randomisation of subjects to intervention and control groups was followed in all experimental primary studies to counteract confounding variables. The reflexology intervention was standardised in all of the primary studies. The control intervention strategy mostly used in the experimental primary studies was non-specific foot massage avoiding specific reflex points and reflex areas on the feet of participants.

A tendency was noted towards favouritism in the utilisation of the experimental design to investigate the efficacy of reflexology in adults with chronic disease. This was an appropriate strategy but lack elements of the total understanding and experience of reflexology as a holistic CAM modality.

The bottom-line findings were consistent across most of the primary studies with a difference in outcome regarding three detached experimental primary studies on chronic diseases such as irritable bowel syndrome, menopausal symptoms and asthma. The conflicting evidence regarding the benefit of reflexology in irritable bowel syndrome, menopausal symptoms and asthma have been disclosed in three detached experimental studies with neutral quality ratings and a different chronic disease as subject in each case without validations made in further studies. Some of the outcomes were intermediate outcomes to the current review question as demonstrated through symptoms of bloatedness, abdominal pain, changes in patterns of diarrhoea/constipation, hot flushes, night sweats, lung function measurements and bronchial histamine challenge tests. Chronic disease is a collective name for a wide scope of different diseases that were chronic in nature and share the common ground of impaired physical vitality, subjective feelings of un-wellness and deficits in quality of life. The bottom line findings and review question was therefore in correlation with chronic disease as collective noun although it consisted of different diseases per se. Therefore the conflicting evidence is handled with caution and further studies should be conducted to verify these outcomes.

Similarities across findings of the included primary studies for evidence analysis were demonstrated through quality ratings, class of evidence, consistency in findings, clinical impact and generalisability respectively.

Experimental studies were all of evidence class A with neutral (Ø) quality ratings, while the systematic reviews were also of evidence class A but with positive (+) quality ratings. The primary studies with non-experimental designs differ in quality ratings of positive (+) and neutral (Ø) respectively. Several primary studies by independent investigators were included in the review and there were some doubts about the adequacy of sample size to avoid type I and type II error.

Consistencies in findings across several independent primary studies support positive benefits of reflexology on sensory symptoms, urinary symptoms anxiety and pain in chronic disease. However some doubts were raised about statistical and clinical significance of the effect size in a few experimental studies as displayed in the data extraction tables of the article (refer to table 2.9). The outcomes of the primary experimental studies appears to relates more to intermediate outcomes of the current review question, while the outcomes of the primary non-experimental studies appears to relate more directly to the current review question. The clinical impact of the evidence is therefore negatively influenced as discussed in the latest manual of ADA (2009:57).

Methodology limitations of small sample sizes and heterogeneity in settings and chronic disease typologies of the included primary studies of experimental design had a very negative influence on the generalisability of the findings and contextualisation to the South African context as discussed in the article. Therefore generalisability should be treated with caution till further studies have been conducted with more rigorous methodology and larger sample sizes. The identified relationship of variables in relation to the grading of conclusion is displayed in table 3.1.

Table 3.1 Identified patterns, similarities, differences, conflicting evidence and possible relationships in findings of study.

Grading the strength of evidence	Patterns	Similarities	Differences	Conflicting evidence	Possible relationships
Quality - Scientific rigour/ validity - Considers design and execution	Experimental design more prevalent than non-experimental design in primary studies	- Primary studies in evidence class A with medium/ neutral quality rating more prevalent in experimental studies - Two systematic reviews in evidence class M with high/ positive quality rating	Primary study in evidence class D with high/ positive quality rating	None	- Class A evidence difficult to draw clear concise conclusions due to study limitations. - Class D evidence able to draw comparisons in similar situations due to explicit philosophical base, data triangulation, richness of data, reflection with field notes, member checking and systematic review validation. - Class M evidence support class A and class D evidence
Consistency of findings	Results reveal no statistical significant difference between intervention and control group although clinical significant differences in measurement were noted	Support positive benefits of reflexology on urinary and sensory symptoms associated with Multiple Sclerosis, decrease in anxiety and pain in cancer patients/palliative care, reduction in frequency of seizures of patients with intractable epilepsy and decrease in pain accompanied with an increase in overall well-being, emotional and spiritual healing effects in women with Fibromyalgia Syndrome	No support for any benefit in patients with Irritable Bowel Syndrome, Menopausal symptoms or Asthma beyond placebo effect.	No benefit of reflexology in irritable bowel syndrome, menopausal symptoms and asthma.	Symptomatic improvements of sensory, urinary, anxiety and pain supported by improvement of overall well-being and vitality to promote quality of life through emotional and spiritual healing as self empowerment strategy to cope with chronic disease.
Quantity	scarcity of studies during 2004 and 2005 scarcity on non-experimental studies	Several experimental studies with relative small sample sizes identified	Only two non-experimental studies with appropriate sample sizes identified	None	Several studies on the effectiveness of efficacy of reflexology (experimental design) but small amount of studies on experience of vitality and well-being as unique subjective dimension.
Clinical impact	- Active involvement of western countries – research of utilization of reflexology in adults with chronic disease - Relative large amount of studies conducted on utilization of reflexology in adults with cancer/ palliative care	- Experimental study outcomes relates to intermediate outcomes of review question - Several studies conclude that reflexology appears to be a non-invasive safe therapy and no adverse effects have been reported in literature - Non-experimental study outcomes relates directly to review question - Doubts about statistical or clinical significance	Few studies promote cost effectiveness of reflexology – to be investigated and researched		Experimental design capture efficacy of reflexology on symptoms and intermediate outcomes, while non-experimental design offer in depth and individualized descriptions of participants experience .
Generalisability	heterogeneity of samples, settings and chronic diseases	- Limitation of small sample sizes in experimental studies - Heterogeneity of sample s , settings and chronic disease in experimental and non-experimental studies	Several studies in cancer patients or palliative care	None	Cancer patients rely on palliative care. AIDS patients rely on care during terminal phase or relapses in South African context.

4. LIMITATIONS, CONCLUSIONS AND RECOMMENDATIONS

The researcher draws the final conclusion statement from the findings of these variables as well as emerging patterns, similarities, differences and possible relationships amongst the variables. The ADA Evidence analysis manual (ADA, 2005) recommended a conclusion grading table to use in writing the final conclusion statement. The adapted conclusion grading table of ADA is displayed in Table 1.12.

Table 1.12: Adapted conclusion grading table of the ADA (adapted from ADA, 2005:44–45; ADA, 2009:63)

GRADING THE STRENGTH OF THE EVIDENCE FOR A CONCLUSION STATEMENT OR RECOMMENDATION					
Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert opinion only	Grade V Grade not assignable
Quality • Scientific rigour / validity • Considers design and execution	Studies with strong design free from design flaws, bias and execution problems to answer review question	Studies of strong design with minor methodological concerns OR Only studies of weaker design	Studies of weak design OR Inconclusive findings due to design flaws, bias or execution problems	No studies available to answer review question	No evidence that pertains to review question
Consistency of findings across studies	Findings generally consistent in direction and size of effect or degree of association and statistical significance with minor exceptions at most	Inconsistency among results of studies with strong design OR consistency with minor exceptions across studies of weaker design	Unexplained inconsistency among results from different studies OR single study unconfirmed by other studies	Conclusion supported solely by statements of informed experts on Reflexology	Not applicable
Quantity • Numbers of studies • Number of subjects in studies	One to several good studies Large number of subjects studies Studies with negative results have sufficiently	Several studies by independent investigators Doubts about adequacy of sample size to avoid Type I	Limited number of studies Low number of subjects studied and / or inadequate	Unsubstantiated by published research studies	Relevant studies have not been done

	large sample sizes for adequate statistical power	and Type II error	sample size within studies		
Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert opinion only	Grade V Grade not assignable
Clinical impact •Importance of studied outcomes •Magnitude of effect	Study outcome relates directly to review question Size of effect is clinically meaningful Significant statistical difference is large	Some doubt about the statistical or clinical significance of the effect	Study outcome is an intermediate outcome for the true outcome of interest OR Size of effect is small or lacks statistical and / or clinical significance	Objective data unavailable	Indicates area for further research
Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert opinion only	Grade V Grade not assignable
Generalizability To the population of interest	Studied population, intervention and outcomes are free from serious doubts about generalizability	Minor doubts about generalizability	Serious doubts about generalizability due to narrow of different study population, intervention or outcomes studied	Generalizability limited to scope of experience	Not applicable

The researcher draws the conclusion statement from the findings of these variables and in relation to answering the review question appropriately.

What evidence is there that the utilisation of reflexology as CAM modality enhances vitality and well-being in the promotion of quality of life in adults with chronic disease?

There is fair evidence that reflexology as CAM modality enhances vitality and well-being in adults with chronic disease to promote quality of life, as demonstrated by improved sensory and urinary symptoms associated with multiple sclerosis; a decrease in anxiety associated with cancer patients during palliative care; improved relaxation, coping and well-being in cancer patients during palliative

care; and reduction in pain together with improvement in overall well-being in patients with fibromyalgia syndrome.

The strength of the evidence is considered fair according to the adapted evidence grading system of the ADA Evidence analysis manual (ADA, 2005).

The quality of included primary studies for review was mostly studies of weaker design; the consistency of findings across studies was consistent, with minor exceptions across studies of weaker design and different types of chronic diseases. The quantity of studies together with the number of subjects were viewed as several studies by independent investigators with doubts concerning the adequacy of sample size to avoid Type I and Type II errors.

According to the ADA conclusion grading table, the clinical impact of the evidence is grade III (limited). However, the clinical impact is debated by the researcher as doubtful concerning the statistical or clinical significance of effect due to the fact that although several studies by independent investigators were included in the review, the overall methodological limitation of small sample sizes used in the primary studies may have impeded significant statistical results. The data collection instruments that were used in the primary studies were not exactly the same in all studies and therefore lack consistency of data collection scales. This may have an impact on overall results. The researcher therefore grades this element with caution as grade III (limited evidence).

The element on generalisability to the population of interest causes serious doubts due to the narrow study population of heterogeneous chronic diseases; therefore, this element is graded as grade III (limited strength of evidence). The contextualisation of findings requires that generalisation of the findings of a study are truly representative of the target population. The target population in the included studies of the review was adults with chronic diseases, such as multiple sclerosis, various cancer typologies, chronic low back pain, irritable bowel syndrome, fibromyalgia syndrome, asthma, intractable epilepsy, diabetic neuropathy and menopausal symptoms. The included primary studies for evidence analysis produced a heterogeneous sample frame with inexplicit categorisation of the various typologies of chronic diseases and therefore limited generalisation.

Representativeness of a sample further relates to the sampling error or the difference between a sample statistic and a population parameter. Sampling error

is not under the researcher's control, as it is caused by chance variations that may occur when a sample is chosen to represent the target population (Brink *et al.*, 2006:124–127; Burns & Grove, 2005:344–355). In all but one of the included studies for review the sample was a non-probability (convenience) sample. The settings of the included studies for review were mostly hospital, outpatient and palliative care settings, which arduously influenced the sample-selection processes. Most of the included studies made use of convenience sampling but improved the representativeness by stringent inclusion and exclusion criteria (Burns & Grove, 2005:350).

This was one way in which the researchers tried to overcome the influence of extraneous variables in the included studies for review, but it was not very successful and lead to inexplicit conclusions in most cases. Most of the included studies for review presented with small sample sizes, which limited generalisation. Sampling error is usually larger with small sample sizes and decreases as the sample size increases (Burns & Grove, 2005:344).

The South African context itself differs from the studied context of the included primary studies of the current review, as to the various typologies of chronic diseases that have been explored. Stroke, cardiovascular diseases, Diabetes Mellitus and AIDS-related diseases are currently more prevalent in South Africa than fibromyalgia syndrome or irritable bowel syndrome, although it is part of the overall scope of health care in South Africa.

The findings of this study should therefore be used with caution. Many of the specific findings may be translated to the South African context and validated in future research.

3.3 RECOMMENDATIONS

The findings of the review enables recommendations to be made for nursing practice, nursing education and nursing research on the utilisation of reflexology as CAM modality for adults with chronic disease to improve comprehensive nursing care delivery to patients. The recommendations that are made from the findings of the study are:

- Reflexology is a holistic therapy that treats the body as a whole and should be evaluated with a holistic approach and appropriate design to complement it. Therefore reflexology should be researched more in depth to understand the knowledge base of reflexology and its holistic action on the human body by utilising mixed methods in whole system research designs.
- Reflexology should be made accessible to patients that choose reflexology as option to empower themselves in the management of their chronic disease or during palliative care to promote comprehensive nursing care in the community.
- Reflexology may contribute to emotional and spiritual healing during palliative care by empowering patients to come to terms with their personal identity and coping more explicitly with physical symptoms of chronic disease.
- Reflexology may contribute positively to community and palliative health care if caregivers and families could be trained by professional reflexologists to deliver simple basic reflexology treatments in the privacy of the home environment to create an individualised community-based inter-active health care system under nursing supervision.

3.3.1 Nursing practice

Reflexology as a CAM modality may be incorporated into nursing practice to make it more accessible to patients with chronic disease or disabilities or those undergoing palliative care to promote well-being and quality of life.

3.3.2 Nursing education

Reflexology as a CAM modality can be included in the nursing curriculum to inform, educate and equip nurses with speciality skills in community care, palliative care, caring for the aged and rehabilitation care to promote well-being and quality of life in patients with chronic diseases.

3.3.3 Nursing research

Future research with appropriate design and a holistic approach to confirm and validate the findings is recommended to enrich the existing knowledge base of nursing and to render more individualised patient care that is holistic in nature to promote well-being and quality of life in patients with chronic diseases.

3.4 LIMITATIONS OF THE STUDY

The integrative literature review was conducted on studies presenting mostly with a neutral quality rating and a mixture of class A and D evidence; therefore, generalisation is limited to the specific context and cannot be generalised to the wider population or context.

3.5 FINAL CONCLUSION

Given the variations in chronic diseases, typology and context the evidence that reflexology as CAM modality benefit patients with chronic disease to promote well-being and quality of life are fair. However more integrative and high quality research are needed to verify and validated the findings of this study in the South African context.

Reflexology appears to be a non-invasive therapy with no reported adverse effects that may enhance vitality and well-being in adults with chronic disease to promote their quality of life. Reflexology is a holistic CAM modality that treats the patient as individual in a unique way to balance underlying energy imbalances and synchronise the body to its own emotional and spiritual healing mechanism to actively pursue wholeness/integrity on physical, psychological and social level. Patients should be informed of the possible benefits and left to decide for themselves if they want to utilise it as part of emotional and spiritual healing to empower themselves in their pursuit towards wholeness/integrity.

Nurses should be educated on reflexology as CAM modality to react informative on patients inquiries and to utilise it as part of community and palliative care in conventional health care practice. Reflexologists and nurses trained in reflexology practice can teach care-givers to utilise reflexology in community and palliative care to promote well-being and quality of life.

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APPENDIX A – SORT LIST

SORT LIST OF IDENTIFIED STUDIES FOR CRITICAL APPRAISAL INTEGRATIVE REVIEW						
Nr	Title	Author	Reference	Design	Rationale	Quality rating
1	<i>Reflexology for symptom relief in patients with cancer</i>	<i>Wilkinson S; Lockhart K; Gambles M et al</i>	<i>Cancer Nursing 2008 31(5) : 354-360</i>	<i>Systematic review</i>	<i>Included</i>	<i>A + CASP 8/10</i>
2	<i>The efficacy of reflexology : systematic review</i>	<i>Wang MY; et al</i>	<i>Journal of Advance Nursing 2008 Jun 62(5) : 512-520</i>	<i>Systematic review</i>	<i>Included</i>	<i>A + CASP 8/10</i>
3	<i>Using Reflexology for Pain Management</i>	<i>Stephenson N.L.N; Dalton J</i>	<i>Journal of Holistic Nursing 2003 21(2):179-191 June</i>	<i>Narrative Review</i>	<i>Included</i>	<i>R - CASP 4/10</i>
4	<i>Other complementary and alternative medicine modalities: acupuncture, magnets, reflexology and homeopathy</i>	<i>Carpenter J S; Neal J G</i>	<i>The American journal of medicine 2005 Dec 19 118(12B) : 109S-117S</i>	<i>Narrative Review</i>	<i>Excluded - on CAM not reflexology alone</i>	<i>N/A</i>
5	<i>Unconventional therapies for cancer and cancer related symptoms</i>	<i>Vickers A J; Cassileth B R</i>	<i>The lancet oncology 2001 April 2(4) : 226-232</i>	<i>Narrative Review :</i>	<i>Excluded - on CAM not reflexology alone</i>	<i>N/A</i>
6	<i>Putting evidence into Practice: Evidence-based interventions for anxiety</i>	<i>Sheldon L K; Swanson S; Dolce A; Marsh K; and Summers J</i>	<i>Clinical Journal of Oncology Nursing 12 (5) : 789-797</i>	<i>Narrative Review</i>	<i>Excluded - on CAM not reflexology alone</i>	<i>N/A</i>
7	<i>Complementary and alternative therapies for treating multiple sclerosis symptoms: a systematic review</i>	<i>Huntley A; Ernst E</i>	<i>Complementary therapies in medicine 2000 Jun 8(2) : 97-105</i>	<i>Systematic review</i>	<i>Excluded - on CAM not reflexology alone</i>	<i>N/A</i>
8	<i>A randomized controlled study of reflexology for the management of chronic low back pain</i>	<i>Poole H; Glenn S; Murphy P</i>	<i>European journal of pain 2007 11 : 878-887</i>	<i>RCT</i>	<i>Included</i>	<i>A Ø CASP 7/10</i>

Nr	Title	Author	Reference	Design	Rationale	Quality rating
9	<i>A single-blind trial of reflexology for irritable bowel syndrome</i>	<i>Tovey P</i>	<i>British journal of general practice 2002 Jan 52(474) : 19-23</i>	<i>RCT</i>	<i>Included</i>	<i>A Ø CASP 6/10</i>
10	<i>Randomised controlled trial of reflexology for menopausal symptoms</i>	<i>Williamson J; White A; Hart A; Ernst E</i>	<i>An international journal of obstetrics and gynaecology BJOG 2002 109 : 1050-1055</i>	<i>RCT</i>	<i>Included</i>	<i>A Ø CASP 8/10</i>
11	<i>Reflexology in the management of low back pain: a pilot randomized controlled trial</i>	<i>Quinn F; Hughes C M; Baxter G D</i>	<i>Complementary therapies in medicine 2008 16 : 3-8</i>	<i>RCT</i>	<i>Included</i>	<i>A Ø CASP 7/10</i>
12	<i>Randomized clinical trial of a combination of reflexology therapy and conventional drug therapy versus the drug therapy alone, in the management of intractable therapy</i>	<i>Dalal K; Tripathi M; Bajpaj V; Saraswat D; Singh A</i>	<i>Epilepsia 2008 49 Suppl 7 : 1-498</i>	<i>RCT</i>	<i>Included</i>	<i>A Ø CASP 7/10</i>
13	<i>A randomized-controlled trial examining the effects of reflexology of patients with chronic obstructive pulmonary disease (COPD)</i>	<i>Wilkinson I S A; Prigmore S; Rayner F</i>	<i>Complementary therapies in clinical practice 2006 12 : 141-147</i>	<i>RCT</i>	<i>Included</i>	<i>A - CASP 4/10</i>
14	<i>Reflexology treatment relieves symptoms of multiple sclerosis :a randomized controlled study</i>	<i>Siev-Ner I; Gamus D; Lerner Geva L; Achiron A</i>	<i>Multiple Sclerosis 2003 9 (part 4) : 356-361</i>	<i>RCT</i>	<i>Included</i>	<i>A Ø CASP 7/10</i>

Nr	Title	Author	Reference	Design	Rationale	Quality rating
15	<i>Reflexology and bronchial asthma</i>	<i>Brygge T; Heinig J H; Collins P; Ronborg S; Gehrchen P M; Hilden J; Heegaard S; Poulsen L K</i>	<i>Respiratory Medicine 2001 95 : 173-179</i>	<i>RCT</i>	<i>Included</i>	<i>A Ø CASP 6/10</i>
16	<i>A pilot study to evaluate the effect of reflexology on mood and symptom rating of advanced cancer patients</i>	<i>Ross C S K; Hamilton J; Macrae G; Docherty C; Gould A; Cornbleet M A</i>	<i>Palliative Medicine 2002 16 : 544-545</i>	<i>RCT</i>	<i>Excluded Intervention not compliant with inclusion criteria</i>	<i>N/A</i>
17	<i>Does reflexology impact on cancer patients' quality of life?</i>	<i>Hodgson H</i>	<i>Nursing standard 2000 14 (31) : 33-38 April 19-25</i>	<i>RCT</i>	<i>Included</i>	<i>A Ø CASP 6/10</i>
18	<i>The effect of reflexology on self-reported joint pain</i>	<i>Schoolmeesters L J</i>	<i>Thesis 2005 Frances Payne Bolton School of Nursing Case Western Reserve University : Doctor of Philosophy</i>	<i>RCT</i>	<i>Excluded Intervention not compliant with inclusion criteria</i>	<i>N/A</i>
19	<i>Nasal irrigation for the alleviation of sino-nasal symptoms</i>	<i>Heatley D.G. McConnell K.E. Kille T.L. Leverson G.E.</i>	<i>Otolaryngology Head Neck Surgery 2001 125(1):44-48 July</i>	<i>RCT</i>	<i>Excluded Intervention not compliant with inclusion criteria</i>	<i>N/A</i>
20	<i>Reflexology and massage in the treatment of type II Diabetic Neuropathy</i>	<i>Destini Kulik</i>	<i>University of the Pacific 2002 Thesis Master of Arts Psychology</i>	<i>Randomised split-plot factorial design</i>	<i>Included</i>	<i>A Ø CASP 7/10</i>
21	<i>The clinical efficacy of reflexology in Nursing Home Residents with Dementia</i>	<i>Hodgson N A; Andersen S</i>	<i>The journal of alternative and complementary medicine 2008 14(3) : 269- 275</i>	<i>Experimental / repeated measures cross-over design</i>	<i>Included</i>	<i>A Ø CASP 6/10</i>

Nr	Title	Author	Reference	Design	Rationale	Quality rating
22	<i>The effects of foot reflexology on Anxiety and pain in patients with breast and lung cancer</i>	Stephenson N L N; Weinrich S P; Tavakoli A S	<i>Oncology Nursing Forum</i> 2000 27(1) : 67-72	Quasi-Experimental cross-over design	<i>Included</i>	A Ø CASP 7/10
23	<i>The effect of foot reflexology on pain in patients with metastatic cancer</i>	Stephenson N; Dalton J; Carlson J	<i>Applied nursing research</i> 2003 November 16(4) : 284-286	Experimental / Repeated measures	<i>Included</i>	A Ø CASP 7/10
24	<i>Partner-Delivered reflexology : Effects on cancer Pain and Anxiety</i>	Stephenson N L; Swanson M; Dalton J; Keefe F J; Engelke M	<i>Oncology Nursing Forum</i> 2007 34(1) : 127-132	Experimental / design	<i>Included</i>	A Ø CASP 7/10
25	<i>Use of reflexology foot massage to reduce anxiety in hospitalized cancer patients in chemotherapy treatment : methodology and outcomes</i>	Quattrin A; et al	<i>Journal of nursing management</i> 2006 March 14(2) : 96-105	Experimental / Comparative group	<i>Included</i>	A Ø CASP 6/10
26	<i>Feasibility of a reflexology and guided imagery intervention during chemotherapy : results of a quasi-experimental study</i>	Wyatt G et al	<i>Oncology Nursing Forum</i> 2007 May 34(3) : 635-642	Quasi-experimental exploratory	<i>Excluded – Reflexology not alone standing modality</i>	N/A
27	<i>The effects of reflexology on foot pain and quality of life in a patient with rheumatoid arthritis: A case report</i>	Khan S; Otter S; Springett K	<i>The Foot</i> 2006 16:112-116	Single Case report	<i>Included</i>	D - CASP 4/10
28	<i>Symptom management and self-care for peripheral neuropathy in HIV/AIDS</i>	Nicholas P K; Kemppainen J K; Carnaval G E	<i>AIDS Care</i> 2007 February 19(2):179-189	Experimental design Descriptive study Cross-sectional design	<i>Excluded – evidence on CAM not on reflexology therapy</i>	N/A

Nr	Title	Author	Reference	Design	Rationale	Quality rating
29	<i>Reflexology versus reflexology and colour therapy combined for treating chronic sinusitis</i>	<i>Gunter A; Van Eeden I; De Jager L</i>	<i>Interdisciplinary Journal 6(1):24-36</i>	<i>Experimental design Non equivalent control group</i>	<i>Excluded Not compliant inclusion criteria – intervention duration ?</i>	N/A
30	<i>Reflexology audit: patient satisfaction, impact on quality of life and availability in Scottish hospices</i>	<i>Milligan M; Fanning M; Hunter S; Tadjali M; Stevens E</i>	<i>International Journal of Palliative Nursing 2002 8(10):489-496</i>	<i>Non-experimental Survey (patient satisfaction) Snapshot survey</i>	<i>Excluded Not compliant inclusion criteria – intervention duration ?</i>	N/A
31	<i>Evaluation of a hospice based reflexology service: a qualitative audit of patient perceptions</i>	<i>Gambles M; Crooke M; Wilkinson S</i>	<i>European Journal of Oncology Nursing 2002 6(1): 37-44</i>	<i>Non-experimental Semi-structured questionnaire Prospective audit</i>	<i>Included</i>	D Ø CASP 6/10
32	<i>Clients' perceptions of the benefits of reflexology on their quality of life</i>	<i>Wright S; Courtney U; Donnelly C; Kenny T; Lavin C</i>	<i>Complementary Therapies in Nursing and Midwifery 2002 8:69-76</i>	<i>Non-experimental Descriptive study Retrospective – patients records</i>	<i>Excluded – anecdotal evidence only</i>	N/A
33	<i>Complementary therapy use by persons with M/S: benefits and research priorities</i>	<i>Esmonde L; Long A F;</i>	<i>Complementary therapies in clinical practice 2008 Aug 14(3) : 176-184</i>	<i>Qualitative Survey Interactive workshop</i>	<i>Excluded – evidence on CAM in general not reflexology alone</i>	N/A
34	<i>The conjoint use of music therapy and reflexology with hospitalized advanced stage cancer patients and their families.</i>	<i>Magill L; Berenson S</i>	<i>Palliative & Supportive Care 2008 Sep 6(3): 289-296</i>	<i>Qualitative Case studies x2</i>	<i>Excluded Reflexology not alone standing modality</i>	N/A

<i>Nr</i>	<i>Title</i>	<i>Author</i>	<i>Reference</i>	<i>Design</i>	<i>Rationale</i>	<i>Quality rating</i>
35	<i>Reflexology for Fibromyalgia Syndrome: A case study.</i>	<i>Gunnarsdottir, T.J.</i>	<i>Dissertation PhD 2007 The Faculty of the Graduate School of the university of Minnesota.</i>	<i>Qualitative case studies x 6</i>	<i>Included</i>	D + CASP 8/10

APPENDIX B – CASP CHECKLISTS

Critical Appraisal Skills Programme (CASP)

making sense of evidence

10 questions to help you make sense of reviews

How to use this appraisal tool

Three broad issues need to be considered when appraising the report of a

systematic review:

- **Is the study valid?**
- **What are the results?**
- **Will the results help locally?**

The 10 questions on the following pages are designed to help you think about these issues systematically.

The first two questions are screening questions and can be answered quickly. If the answer to both is “yes”, it is worth proceeding with the remaining questions.

You are asked to record a “yes”, “no” or “can’t tell” to most of the questions. A number of italicised prompts are given after each question.

These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

The 10 questions are adapted from Oxman AD, Cook DJ, Guyatt GH, Users’ guides to the medical literature. VI. How to use an overview. JAMA 1994; 272 (17): 1367-1371

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Screening Questions

1. Did the review ask a clearly-focused question? ☐ Yes ☐ Can't tell ☐ No

Consider if the question is 'focused' in terms of:

- the population studied
- the intervention given or exposure
- the outcomes considered

2. Did the review include the right type of study? ☐ Yes ☐ Can't tell ☐ No

Consider if the included studies:

- address the review's question
- have an appropriate study design

Is it worth continuing?

Detailed Questions

3. Did the reviewers try to identify all ☐ Yes ☐ Can't tell ☐ No relevant studies?

Consider:

- which bibliographic databases were used
- if there was follow-up from reference lists
- if there was personal contact with experts
- if the reviewers searched for unpublished studies
- if the reviewers searched for non-English-language studies

4. Did the reviewers assess the quality of the ☐ Yes ☐ Can't tell ☐ No included studies?

Consider:

- if a clear, pre-determined strategy was used to determine which studies were included. Look for:
 - a scoring system
 - more than one assessor

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5. If the results of the studies have been ☐ Yes ☐ Can't tell ☐ No combined, was it reasonable to do so?

Consider whether:

- the results of each study are clearly displayed*
- the results were similar from study to study*
(look for tests of heterogeneity)
- the reasons for any variations in results are discussed*

6. How are the results presented and what is the main result?

Consider:

- how the results are expressed (e.g. odds ratio, relative risk, etc.)*
- how large this size of result is and how meaningful it is*
- how you would sum up the bottom-line result of the review in one sentence*

7. How precise are these results?

Consider:

- if a confidence interval were reported. Would your decision about whether or not to use this intervention be the same at the upper confidence limit as at the lower confidence limit?*
- if a p-value is reported where confidence intervals are unavailable*

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8. Can the results be applied to the local ☐ Yes ☐ Can't tell ☐ No population?

Consider whether:

- the population sample covered by the review*

could be different from your population in ways

that would produce different results

*– your local setting differs much from that of the
review*

*– you can provide the same intervention in your
setting*

9. Were all important outcomes considered? ☐ Yes ☐ Can't tell ☐ No

Consider outcomes from the point of view of the:

– individual

– policy makers and professionals

– family/carers

– wider community

10. Should policy or practice change as a result of ☐ Yes ☐ Can't tell ☐ No

the evidence contained in this review?

Consider:

– whether any benefit reported outweighs any

harm and/or cost. If this information is not

reported can it be filled in from elsewhere?

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Critical Appraisal Skills Programme (CASP)

making sense of evidence

10 questions to help you make sense of randomised controlled trials

How to use this appraisal tool

Three broad issues need to be considered when appraising the report of a

randomised controlled trial:

- **Is the trial valid?**
- **What are the results?**
- **Will the results help locally?**

The 10 questions on the following pages are designed to help you think about these issues systematically.

The first two questions are screening questions and can be answered quickly. If the answer to both is “yes”, it is worth proceeding with the remaining questions.

You are asked to record a “yes”, “no” or “can’t tell” to most of the questions. A number of italicised prompts are given after each question.

These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

The 10 questions are adapted from Guyatt GH, Sackett DL, and Cook DJ, Users’ guides to the medical literature. II. How to use an article about therapy or prevention. *JAMA* 1993; 270 (21): 2598-2601 and *JAMA* 1994; 271(1): 59-63

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Screening Questions

1. Did the study ask a clearly-focused question? ☐ Yes ☐ Can't tell ☐ No

Consider if the question is 'focused' in terms of:

- the population studied*
- the intervention given*
- the outcomes considered*

2. Was this a randomised controlled trial (RCT) ☐ Yes ☐ Can't tell ☐ No

and was it appropriately so?

Consider:

- why this study was carried out as an RCT*
- if this was the right research approach for the*

question being asked

Is it worth continuing?

Detailed Questions

3. Were participants appropriately allocated to ☐ Yes ☐ Can't tell ☐ No

intervention and control groups?

Consider:

- how participants were allocated to intervention and control groups. Was the process truly random?*
- whether the method of allocation was described. Was a method used to balance the randomization, e.g. stratification?*
- how the randomization schedule was generated and how a participant was allocated to a study group*
- if the groups were well balanced. Are any differences between the groups at entry to the*

trial reported?

*– if there were differences reported that might
have explained any outcome(s) (confounding)*

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4. Were participants, staff and study personnel ☐ Yes ☐ Can't tell ☐ No

'blind' to participants' study group?

Consider:

- the fact that blinding is not always possible*
- if every effort was made to achieve blinding*
- if you think it matters in this study*
- the fact that we are looking for 'observer bias'*

5. Were all of the participants who entered the ☐ Yes ☐ Can't tell ☐ No

trial accounted for at its conclusion?

Consider:

- if any intervention-group participants got a control-group option or vice versa*
- if all participants were followed up in each study group (was there loss-to-follow-up?)*
- if all the participants' outcomes were analysed by the groups to which they were originally allocated (intention-to-treat analysis)*
- what additional information would you liked to have seen to make you feel better about this*

6. Were the participants in all groups followed ☐ Yes ☐ Can't tell ☐ No

up and data collected in the same way?

Consider:

- if, for example, they were reviewed at the same time intervals and if they received the same amount of attention from researchers and health workers. Any differences may introduce performance bias.*

7. Did the study have enough participants to ☐ Yes ☐ Can't tell ☐ No
minimise the play of chance?

Consider:

*– if there is a power calculation. This will estimate
how many participants are needed to be
reasonably sure of finding something important
(if it really exists and for a given level of
uncertainty about the final result).*

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8. How are the results presented and what is the main result?

Consider:

- if, for example, the results are presented as a proportion of people experiencing an outcome, such as risks, or as a measurement, such as mean or median differences, or as survival curves and hazards*
- how large this size of result is and how meaningful it is*
- how you would sum up the bottom-line result of the trial in one sentence*

9. How precise are these results?

Consider:

- if the result is precise enough to make a decision*
- if a confidence interval were reported. Would your decision about whether or not to use this intervention be the same at the upper confidence limit as at the lower confidence limit?*
- if a p-value is reported where confidence intervals are unavailable*

10. Were all important outcomes considered so ☐ Yes ☐ Can't tell ☐ No

the results can be applied?

Consider whether:

- the people included in the trial could be different from your population in ways that would produce different results*

– *your local setting differs much from that of the trial*

– *you can provide the same treatment in your setting*

Consider outcomes from the point of view of the:

– *individual*

– *policy maker and professionals*

– *family/carers*

– *wider community*

Consider whether:

– *any benefit reported outweighs any harm and/or cost. If this information is not reported can it be filled in from elsewhere?*

– *policy or practice should change as a result of the evidence contained in this trial*

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Critical Appraisal Skills Programme (CASP)

making sense of evidence

10 questions to help you make sense of qualitative research

This assessment tool has been developed for those unfamiliar with qualitative research and its theoretical perspectives. This tool presents a number of questions that deal very broadly with some of the principles or assumptions that characterise qualitative research. It is *not a definitive guide* and extensive further reading is recommended.

How to use this appraisal tool

Three broad issues need to be considered when appraising the report of qualitative research:

- **Rigour: has a thorough and appropriate approach been applied to**
- **key research methods in the study?**
- **Credibility: are the findings well presented and meaningful?**
- **Relevance: how useful are the findings to you and your organisation?**

The 10 questions on the following pages are designed to help you think about these issues systematically.

The first two questions are screening questions and can be answered quickly. If the answer to both is “yes”, it is worth proceeding with the remaining questions.

A number of italicised prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

The 10 questions have been developed by the national CASP collaboration for qualitative methodologies.

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Screening Questions

1. Was there a clear statement of the aims ☐ Yes ☐ No
of the research?

Consider:

- *what the goal of the research was*
- *why it is important*
- *its relevance*

2. Is a qualitative methodology appropriate? ☐ Yes ☐ No

Consider:

- *if the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants*

Is it worth continuing?

Detailed questions

Appropriate research design

3. Was the research design appropriate to Write comments here
address the aims of the research?

Consider:

- *if the researcher has justified the research design (e.g. have they discussed how they decided which methods to use?)*

Sampling

4. Was the recruitment strategy appropriate Write comments here
to the aims of the research?

Consider:

- *if the researcher has explained how the participants were selected*
- *if they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study*
- *if there are any discussions around recruitment (e.g. why some people chose not to take part)*

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Data collection

5. Were the data collected in a way that Write comments here **addressed the research issue?**

Consider:

- if the setting for data collection was justified*
- if it is clear how data were collected (e.g. focus group, semi-structured interview etc)*
- if the researcher has justified the methods chosen*
- if the researcher has made the methods explicit (e.g. for interview method, is there an indication of how interviews were conducted, did they used a topic guide?)*
- if methods were modified during the study. If so, has the researcher explained how and why?*
- if the form of data is clear (e.g. tape recordings, video material, notes etc)*
- if the researcher has discussed saturation of data*

Reflexivity (research partnership relations/recognition of researcher bias)

6. Has the relationship between researcher and Write comments here **participants been adequately considered?**

Consider whether it is clear:

- if the researcher critically examined their own role, potential bias and influence during:*
 - formulation of research questions*
 - data collection, including sample recruitment and choice of location*
- how the researcher responded to events during the study and whether they considered the implications of any changes in the research design*

Ethical Issues

7. Have ethical issues been taken into Write comments here **consideration?**

Consider:

- if there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were*

maintained

- *if the researcher has discussed issues raised by the study (e. g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)*
- *if approval has been sought from the ethics committee*

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Data Analysis

8. Was the data analysis sufficiently rigorous? Write comments here

Consider:

- *if there is an in-depth description of the analysis process*
- *if thematic analysis is used. If so, is it clear how the categories/themes were derived from the data?*
- *whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process*
- *if sufficient data are presented to support the findings*
- *to what extent contradictory data are taken into account*
- *whether the researcher critically examined their own role, potential bias and influence during analysis and selection of data for presentation*

Findings

9. Is there a clear statement of findings? Write comments here

Consider:

- *if the findings are explicit*
- *if there is adequate discussion of the evidence both for and against the researcher's arguments*
- *if the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst.)*
- *if the findings are discussed in relation to the original research questions*

Value of the research

10. How valuable is the research? Write comments here

Consider:

- *if the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature?)*
- *if they identify new areas where research is necessary*
- *if the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used*

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APPENDIX C – ADA CHECKLISTS

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Appendix 7: Evidence Abstract Worksheet Template

Citation:																							
Study Design:																							
Class:	Based on classes of evidence reports (Table 2.3)																						
Quality Rating:	+, Ø, - Based on Quality Criteria Checklist																						
Research Purpose:																							
Inclusion Criteria:																							
Exclusion Criteria:																							
Description of Study Protocol:	Recruitment Design (These prompts assist you in determining which information to abstract from research article.) Blinding used (if applicable) Intervention (if applicable) Statistical Analysis																						
Data Collection Summary:	Timing of Measurements Dependent Variables - Variable 1: brief description (how measured?) - Variable 2: brief description (how measured?) - etc. Independent Variables Control Variables																						
Description of Actual Data Sample:	Initial N: (e.g., 731 (298 males, 433 females)) Attrition (final N): Age: Ethnicity: Other relevant demographics: Anthropometrics (e.g., were groups same or different on important measures) Location:																						
Summary of Results:	<table border="1"> <thead> <tr> <th>Variables</th> <th>Treatment Group Measures and confidence intervals</th> <th>Control group Measures and confidence intervals</th> <th>Statistical Significance of Group Difference</th> </tr> </thead> <tbody> <tr> <td>Dep var 1</td> <td>Mean, CI. e.g., 4.5±2.2</td> <td>Mean, CI. e.g., 1.5±2.0</td> <td>Stat signif difference between groups e.g., p=.002</td> </tr> <tr> <td>Dep var 2</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Etc.</td> <td></td> <td></td> <td></td> </tr> <tr> <td colspan="4">Other Findings</td> </tr> </tbody> </table>			Variables	Treatment Group Measures and confidence intervals	Control group Measures and confidence intervals	Statistical Significance of Group Difference	Dep var 1	Mean, CI. e.g., 4.5±2.2	Mean, CI. e.g., 1.5±2.0	Stat signif difference between groups e.g., p=.002	Dep var 2				Etc.				Other Findings			
Variables	Treatment Group Measures and confidence intervals	Control group Measures and confidence intervals	Statistical Significance of Group Difference																				
Dep var 1	Mean, CI. e.g., 4.5±2.2	Mean, CI. e.g., 1.5±2.0	Stat signif difference between groups e.g., p=.002																				
Dep var 2																							
Etc.																							
Other Findings																							
Author Conclusion:																							
Review Comments:	<i>Italicize reviewer and expert panel comments.</i>																						
Funding Source	Determine the funding source: Government, Industry, University/Hospital, Not-for-Profit and/or Other.																						

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Appendix 8: Quality Criteria Checklist: Primary Research

Symbols Used

- + **Positive:** Indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.
- **Negative:** Indicates that these issues have not been adequately addressed.
- ∅ **Neutral:** Indicates that the report is neither exceptionally strong nor exceptionally weak.

Quality Criteria Checklist: Primary Research

RELEVANCE QUESTIONS		Yes	No	Unclear	N/A
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epi studies)				
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?				
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?				
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)				
<i>If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.</i>					
VALIDITY QUESTIONS		Yes	No	Unclear	N/A
1.	Was the research question clearly stated?				
1.1	Was the specific intervention(s) or procedure (independent variable(s)) identified?				
1.2	Was the outcome(s) (dependent variable(s)) clearly indicated?				
1.3	Were the target population and setting specified?				
2.	Was the selection of study subjects/patients free from bias?				
2.1	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?				
2.2	Were criteria applied equally to all study groups?				
2.3	Were health, demographics, and other characteristics of subjects described?				
2.4	Were the subjects/patients a representative sample of the relevant population?				
3.	Were study groups comparable?				
3.1	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)				
3.2	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?				
3.3	Were concurrent controls used? (Concurrent preferred over historical controls.)				
3.4	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?				
3.5	If case control study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)				
3.6	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?				
4.	Was method of handling withdrawals described?				
4.1	Were follow up methods described and the same for all groups?				
4.2	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)				
4.3	Were all enrolled subjects/patients (in the original sample) accounted for?				
4.4	Were reasons for withdrawals similar across groups?				

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4.5	If diagnostic test, was decision to perform reference test not dependent on results of test under study?				
5.	Was <u>blinding</u> used to prevent introduction of bias?	Yes	No	Unclear	N/A
5.1	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?				
5.2	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)				
5.3	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?				
5.4	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?				
5.5	In diagnostic study, were test results blinded to patient history and other test results?				
6.	Were <u>intervention/therapeutic regimens/exposure factor or procedure</u> and any <u>comparison(s)</u> described in detail? Were <u>intervening factors</u> described?	Yes	No	Unclear	N/A
6.1	In RCT or other intervention trial, were protocols described for all regimens studied?				
6.2	In observational study, were interventions, study settings, and clinicians/provider described?				
6.3	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?				
6.4	Was the amount of exposure and, if relevant, subject/patient compliance measured?				
6.5	Were co-interventions (e.g., ancillary treatments, other therapies) described?				
6.6	Were extra or unplanned treatments described?				
6.7	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?				
6.8	In diagnostic study, were details of test administration and replication sufficient?				
7.	Were <u>outcomes</u> clearly defined and the <u>measurements valid and reliable</u>?	Yes	No	Unclear	N/A
7.1	Were primary and secondary endpoints described and relevant to the question?				
7.2	Were nutrition measures appropriate to question and outcomes of concern?				
7.3	Was the period of follow-up long enough for important outcome(s) to occur?				
7.4	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?				
7.5	Was the measurement of effect at an appropriate level of precision?				
7.6	Were other factors accounted for (measured) that could affect outcomes?				
7.7	Were the measurements conducted consistently across groups?				
8.	Was the <u>statistical analysis</u> appropriate for the study design and type of outcome indicators?	Yes	No	Unclear	N/A
8.1	Were statistical analyses adequately described the results reported appropriately?				
8.2	Were correct statistical tests used and assumptions of test not violated?				
8.3	Were statistics reported with levels of significance and/or confidence intervals?				
8.4	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?				
8.5	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?				
8.6	Was clinical significance as well as statistical significance reported?				
8.7	If negative findings, was a power calculation reported to address type 2 error?				
9.	Are <u>conclusions supported by results</u> with biases and limitations taken into consideration?	Yes	No	Unclear	N/A
9.1	Is there a discussion of findings?				
9.2	Are biases and study limitations identified and discussed?				
10.	Is bias due to study's <u>funding or sponsorship</u> unlikely?	Yes	No	Unclear	N/A
10.1	Were sources of funding and investigators' affiliations described?				
10.2	Was there no apparent conflict of interest?				
MINUS/NEGATIVE (-) If most (six or more) of the answers to the above validity questions are "No," the report should be designated with a minus (-) symbol on the Evidence Worksheet.					

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NEUTRAL (⊖)

If the answers to validity criteria questions 2, 3, 6, and 7 do not indicate that the study is exceptionally strong, the report should be designated with a neutral (⊖) symbol on the Evidence Worksheet.

PLUS/POSITIVE (+)

If most of the answers to the above validity questions are "Yes" (including criteria 2, 3, 6, 7 and at least one additional "Yes"), the report should be designated with a plus symbol (+) on the Evidence Worksheet.

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Appendix 9: Quality Criteria Checklist: Review Article

Symbols Used

+ **Positive:** Indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

-- **Negative:** Indicates that these issues have not been adequately addressed.

Ø **Neutral:** Indicates that the report is neither exceptionally strong nor exceptionally weak.

Quality Criteria Checklist Review Articles

RELEVANCE QUESTIONS				
1.	Will the answer if true, have a direct bearing on the health of patients?	Yes	No	Unclear N/A
2.	Is the outcome or topic something that patients/clients/population groups would care about?	Yes	No	Unclear N/A
3.	Is the problem addressed in the review one that is relevant to dietetics practice?	Yes	No	Unclear N/A
4.	Will the information, if true, require a change in practice?	Yes	No	Unclear N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.				
VALIDITY QUESTIONS				
1.	Was the question for the review clearly focused and appropriate?	Yes	No	Unclear N/A
2.	Was the search strategy used to locate relevant studies comprehensive? Were the databases searched and the search terms used described?	Yes	No	Unclear N/A
3.	Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased?	Yes	No	Unclear N/A
4.	Was there an appraisal of the quality and validity of studies included in the review? Were appraisal methods specified, appropriate, and reproducible?	Yes	No	Unclear N/A
5.	Were specific treatments/interventions/exposures described? Were treatments similar enough to be combined?	Yes	No	Unclear N/A
6.	Was the outcome of interest clearly indicated? Were other potential harms and benefits considered?	Yes	No	Unclear N/A
7.	Were processes for data abstraction, synthesis, and analysis described? Were they applied consistently across studies and groups? Was there appropriate use of qualitative and/or quantitative synthesis? Was variation in findings among studies analyzed? Were heterogeneity issues considered? If data from studies were aggregated for meta-analysis, was the procedure described?	Yes	No	Unclear N/A
8.	Are the results clearly presented in narrative and/or quantitative terms? If summary statistics are used, are levels of significance and/or confidence intervals included?	Yes	No	Unclear N/A
9.	Are conclusions supported by results with biases and limitations taken into consideration? Are limitations of the review identified and discussed?	Yes	No	Unclear N/A
10.	Was bias due to the review's funding or sponsorship unlikely?	Yes	No	Unclear N/A
MINUS/NEGATIVE (-)				
If most (six or more) of the answers to the above validity questions are "No," the review should be designated with a minus (-) symbol on the Evidence Quality Worksheet.				
NEUTRAL (Ø)				
If the answer to any of the first four validity questions (1-4) is "No," but other criteria indicate strengths, the review should be designated with a neutral (Ø) symbol on the Evidence Worksheet.				
PLUS/POSITIVE (+)				
If most of the answers to the above validity questions are "Yes" (must include criteria 1, 2, 3, and 4), the report should be designated with a plus symbol (+) on the Evidence Worksheet.				

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Appendix 10: Important Considerations from Checklist by Study Design

Study design type	Distinguishing characteristics of design	Most important considerations (from checklist)*
EXPERIMENTAL & QUASI-EXPERIMENTAL STUDIES	(Investigator manipulated independent variable always control group)	
Randomized controlled trial (Preferred for therapy and prevention questions)	investigators manipulates treatment/intervention (independent variable) randomization to groups	3.1, 3.2, 4.3 2.1, 2.3, 5.1, 5.2, 6.1, 6.3–6.7, 7.4
Nonrandomized trial (Frequently used for therapy and prevention questions)	investigators manipulates treatment/intervention (independent variable)	2.1, 2.3, 3.1-3.3, 4.3 5.1, 5.2, 6.1, 6.3–6.7, 7.1–7.7
OBSERVATIONAL STUDIES	(Comparisons made)	
Comparison of 2 or more groups (also called prospective cohort) (Preferred for etiology, causation, or harm questions)	comparison of existing "convenient" groups getting different interventions or exposures	2.1, 2.2, 4.3, 4.4, 7.1, 7.3, 7.4, 7.6, 7.7, 8.5 2.3, 3.2, 3.3, 5.2, 5.3, 6.2–6.7
Single group before-after or time series	subject serves as own control	2.1, 2.3, 2.4, 6.2, 7.4, 7.6 4.3, 5.1, 5.2, 6.3–6.7, 7.1–7.3, 7.5 3 - NA**
Sensitivity & specificity of diagnostic test (Preferred for diagnosis questions)	dichotomous (yes/no) outcome comparison with "gold standard"	3g, 4e, 5e 2.4, 6.8, 7.6
EPIDEMIOLOGICAL ANALYTIC STUDIES	(Comparisons constructed analytically, groups created post hoc)	
Cohort study (Preferred for natural history and prognosis questions)	membership based on defining characteristic or factor	2.1, 4.3, 7.1, 7.3, 7.4, 7.6, 8.5 2.3, 3.4, 5.3, 6.3
Case-control study (Preferred for etiology, causation, or harm questions)	"cases" with outcome identified then "matched" with non-cases (controls) from same population look back for exposure	2.1, 3.5, 4.3, 7.3, 7.4, 7.6, 7.7 2.3, 5.4, 6.3, 6.4
Cross-sectional study (Preferred for diagnosis questions) (Used for etiologic, causation, or harm questions)	outcome (dependent variable) and exposure (independent variable) measured at same time	4.3, 7.4, 7.6 2.1, 2.3, 2.4, 3.4, 5.3, 6.8, 7.2, 7.4–7.6 3 - NA, if comparison groups are not constructed
DESCRIPTIVE STUDIES	(No comparison)	
Case series	describe process and outcomes prospectively, "natural history" with no intervention	2.1, 4.3, 6.5, 6.6, 7.1, 7.4, 7.6 2.3, 2.4, 5.2, 5.3, 7.2, 7.3 3 - NA

*See: *Quality Criteria Checklist*: Primary Research. **Bolded items are most important for study design.** The other (not bold) items are also common threats to validity in study type.

**NA = not applicable