

Semester * 2023/24**MA Health & Wellbeing & MSc Infection Prevention & Control
Dissertation Cover Sheet**

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Student Reflections on the Assignment:

The accumulation of 3 years study on the MA Health & Wellbeing has been well supported, focused and enjoyable. The past year of research on my chosen subject area has been instrumental in building my knowledge base and confidence engaging with research papers. This has translated in the outer world, in terms of stepping out of my comfort zone and connecting with professionals in the field of complementary therapies & integrative healthcare.

As this was my first experience writing a systematic review of the literature, it was a positive challenge to make decisions about which themes to include or expand upon. The creation of extraction forms as 'worksheets' were immensely helpful to me in terms of processing and synthesising information.

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**The Clinical Evidence-base for the Use of Massage and
Foot Reflexology in Integrative Oncology.**

Dissertation submitted in partial fulfilment of the requirements
for the degree of MSc Infection Prevention & Control.

Student No: 022625

Month/Year: December 2023

University of the Highlands & Islands

'Touch is ten time stronger than verbal or emotional contact and it affects nearly everything we do....We forget that touch is not only basic to our species, but the key to it'.

(Field, 2014, p. 225)

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'Integrative oncology provides a framework for bringing together traditional, complementary and integrative medicine & standard oncologic care'.

(Mao & Salicrup 2021, p.2)

Abstract

Cancer is a leading cause of mortality world-wide. In a recent systematic review, Candy (2020) tells us that people with advanced illness including cancers, can experience a range of problems such as anxiety, fatigue and pain for which conventional treatments may not provide sufficient relief. Furthermore, other studies (Cassileth 2004 and Ernst 2009) have found that massage can reduce muscle fatigue, improve blood flow, relax mood as well as relieve cancer symptoms such as anxiety, depression, pain and nausea. Non-pharmaceutical therapies known as Complementary and Alternative medicine (CAM) are becoming a more popular supportive care option for people receiving cancer treatment (Calcagni & Quitard 2019). Although there is high prevalence of CAM provider use in all world regions, there are in fact large country differences. The prevalence estimate of CAM from all regions of the world to be 26.4% ranging from 25.9 to 26.9% (Peltzer & Pengpid 2018).

Candy (2020) says there are a number of trials that have evaluated massage and reflexology (including aromatherapy) but there has been limited systematic, *critical review* of the evidence about the effectiveness of these therapies in palliative care. Reviews which generate conclusions beyond single studies, and instead across studies will provide more informed recommendations for funders, clinical providers' and future research. Moreover, Black (2009) points out that no strategy for improving the evidence-base for complementary therapies would be complete without investment in work to address some broad categories of questions in CAM. These include; *whether* something works (effect of an intervention); *how* something works (understanding the mechanisms of action); and *how much* something works (measurement & an important factor in cost-effectiveness). Therefore, a paradigm which includes, not procludes the importance of contextual factors is desirable. A leading researcher Wyatt (2012) states that future research should consider cost-effectiveness, physiological mechanisms of action through biomarkers and the potential for involving lay partners in therapy for patients with breast cancer as supportive care. Studies which investigate the long-term efficacy for example on vital signs are needed (Jing 2022). Understanding the significance of changes in vital signs can provide additional clinical help to better predict disease progression and prognosis

(Kamata 2020). This has implications for research on cancer survivorship. Psychiatrists are in a unique position to leverage the benefits of integrative therapies in their own work with survivors (Cassileth 2014).

Whole-system research is an emerging discipline which may offer a new approach to measuring outcomes and mechanisms of action (Whatley 2023). Observational, pragmatic trials are not restricted by the confines of randomized-controlled trials outcomes; can accommodate the holistic nature of massage and reflexology; and includes qualitative data which should not be subtracted from the overall effects (placebo and contextual effects).

Until recently there was *no* peer review published literature that has summarized and analysed the development of foot reflexology.

Acknowledgments

As this dissertation took the form of a systematic review of the literature, it did not involve interviewing procedures. However, there must be acknowledgement of the support and guidance from course leader Rachel Erskine, at Lews Castle College, UHI. Rachel has supported the planning and research process through to the finalisation of this systematic review. The professional support received has facilitated learning.

Glossary

Affective Touch – a complex phenomenon that depends on other bottom-up or bottom-down processes associated with the manner in which individuals engage in friendly physical contact (Schirmer & McGlone 2022).

Adverse Reaction – unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred (White 2014).

Contextual factors – the individual (interactive and interdependent) elements which characterise the context-sensitivity of the therapeutic interactions. It includes environment the treatment is administered in. The ‘atmosphere around the treatment’ or ‘contextual healing’. Contextual factors can act independently (Rossetini 2018).

Complex Interventions – are non-standard interventions, having different forms in different contexts while still conforming to specific theory-driven processes. There are many other definitions of complex interventions. These tend frequently to emphasize that they have multiple interacting components and non-linear causal pathways. In the literature, they are often contrasted with ‘simple’ interventions which are generally seen as having simple, linear pathways linking the intervention to its outcome (Petticrew 2011).

Cost-effectiveness studies – economic analyses which sit alongside clinical studies. These are desirable because they broaden the scope of information available on particular interventions and can effectively provide information with high internal validity (Ramsey 2015).

Cancer survivorship - Cancer survivors were defined according to the National Cancer Institute definition that states:

‘a person is considered to be a survivor in cancer from the time of diagnosis until end of life’

(Ali 2015, p.10).

There is limited understanding of the effects of cancer and cancer treatment in the context of normal ageing and lifestyle patterns. We do know that anxiety, depression and fear of recurrence are common in cancer survivors and some may experience the symptoms of post-traumatic stress.

Effectiveness studies – the question of whether the whole intervention including all the non-specific effects generates positive outcomes. ‘Non-specific’ aspects of treatment include aspects of the experience which are not about the physical intervention; context, healthcare setting, therapeutic relationship, the expectations of the individual (Black 2009).

Efficacy studies – the question of whether a specific intervention works and how it works. Often this work focuses on testing what the underlying mechanisms of action for the intervention might be; chains of cause and effect that might explain the positive (or negative) impact of the physical intervention at the heart of the practice (Black 2009).

Evidence-based medicine – concept emerged in 1980s and is defined as:

‘combined integration of the best available research evidence along with clinical expertise while considering our patients values and circumstances’.

(Latte-Naor 2022, p.10)

Grey literature - can be defined as:

‘that which is produced on all levels of Government, academics, business and industry in print and electronic formats including; reports, thesis, conference proceedings and official documents not published commercially.’

(Charrois 2015, p2)

Healing crisis - can be defined as;

‘Temporary worsening of existing problems/symptoms’ (White 2014, p.407).

Complementary and alternative practitioners regard a healing crisis as a positive sign that predicts subsequent improvement in condition. It is seen to be a sign that the body's self-healing potential has been activated. There are only a few examples of research into this concept although the phenomenon has been widely reported for centuries (Mackereth 1999).

Integrative Oncology - There is currently no accepted definition of integrative oncology but it is generally understood to refer to the use of a combination of complementary therapies in conjunction with conventional cancer treatments. Massage and reflexology are therapeutic modalities which are nestled within integrative oncology with the aim of optimizing health, quality of life, and clinical outcomes across the cancer care continuum. Defining the term more succinctly will enable more focused effort to advance research, practice and education to benefit millions of cancer patients and survivors around the globe (Claudia 2017).

Incidence - The number of new cases arising in a specified population over a period of time. The cancer incidence rate provides the average risk of developing a cancer (Cancer Today 2020).

Massage - Massage is one of the most known therapeutic approaches dating back to 1600BC. Our ancestors found this method of using touch could relieve pain and heal injuries (Spinu 2020). Swedish massage is more commonly used for relaxation and deep tissue massage to alleviate pain (Majchrzycki 2014).

Mortality - The number of deaths due to cancer occurring within a specified population over a given period of time (Cancer Today 2020).

Paradigm - The word has its aetiology in Greek where it means 'pattern'. In educational research the term paradigm is used to describe a researcher's 'world view'. It can be understood in different ways; an epistemological stance; a set of

shared beliefs among members of a speciality area and as a model example of research (Kivunja 2017).

Placebo effect - beneficial effects that are attributable to the brain-mind responses to the context in which a treatment is delivered rather than to specific actions of a drug/intervention. They are mediated by diverse processes including learning, expectations and social cognition (Wager & Atlas 2015).

Post-traumatic growth (PTG) – the positive psychological change experienced after the struggle of a challenging life event (cancer). It can be experienced in different important life domains in the development of an increased appreciation of life, deeper relationships, higher spiritual thrive (Blickle 2024).

Prevalence - The number of individuals within a defined population who have been diagnosed with and who are still alive at any given point in time (Cancer Today 2020).

Randomized-controlled studies – prospective studies that measure the effectiveness of a new intervention or treatment. Population is selected; participants recruited and randomly assigned to either the *intervention* or *comparator* group (there must be no knowledge of which group the participant will be allocated to – concealment). Automated randomized systems are often used (Hariton & Locascio 2018).

Reflexology - has been defined as;

‘a Chinese and Indian system of diagnosis and treatment dating from 3000BC based on the belief that the whole body is represented on the foot (mostly the sole) and that the internal organs can be stimulated by pressing particular areas of the foot.’

(Ernst, 2009, p.5)

Spirituality – an intentional total experience that quietens the mind, keeps a person in the present moment with a positive cognitive frame and altered emotional states including peace and tranquility (Miller 2023).

Systematic reviews - can be defined as:

‘a review of existing research using explicit, accountable rigorous research methods’.
(Gough 2017, p.4).

Centre for Evidence Based Medicine at Oxford University defines systematic reviews (SR) as:

‘the application of strategies designed to limit bias in the assembly, critical appraisal and synthesis of all relevant studies on a specific topic.’

(Baird, 2018, p.9)

Traditional, alternative & complementary medicine (CAM/T&CM) - Traditional & complementary & alternative medicine can be defined as health practices not part of conventional medicine (Nakandi 2023). Indeed, it draws from the knowledge, beliefs and centuries old indigenous peoples (Wiesener 2012). The World Health Organization has loosely defined it as;

‘a broad set of health care practices that are not part of the country’s own tradition and are not integrated into the dominant health care systems.’

(World Health Organization 2019).

Wellbeing - In the absence of an agreed definition, many synonyms, descriptions, lists of wellbeing components or determinants are used interchangeably when wellbeing is discussed, making it hard to compare wellbeing research studies. Modern wellbeing research has focused on many subjective measures of wellbeing (SWB) and a number of theories exists including reversal theory (Apter 2007); authentic happiness theory (Seligman 2002); flow-theory (Csikszentmihalyi 2008) & the self-realisation theory (Waterman 1993); The general consensus is a recognition of the incorporation of both hedonistic and eudemonic components (Simons & Baldwin 2021).

Whole-systems approach (WSA) - is a hybrid phenomenon that stretches the boundaries of biomedical research to better accommodate diverse, holistic healthcare approaches (Ijaz 2018).

Before reading this dissertation, it will be worthwhile to study the next few images which show interesting background global information in relation to the incidence, mortality and prevalence of cancer. This visual aid will aid contextual understanding of the paper.

Estimated age-standardized incidence rates (World) in 2020, all cancers, both sexes, all ages

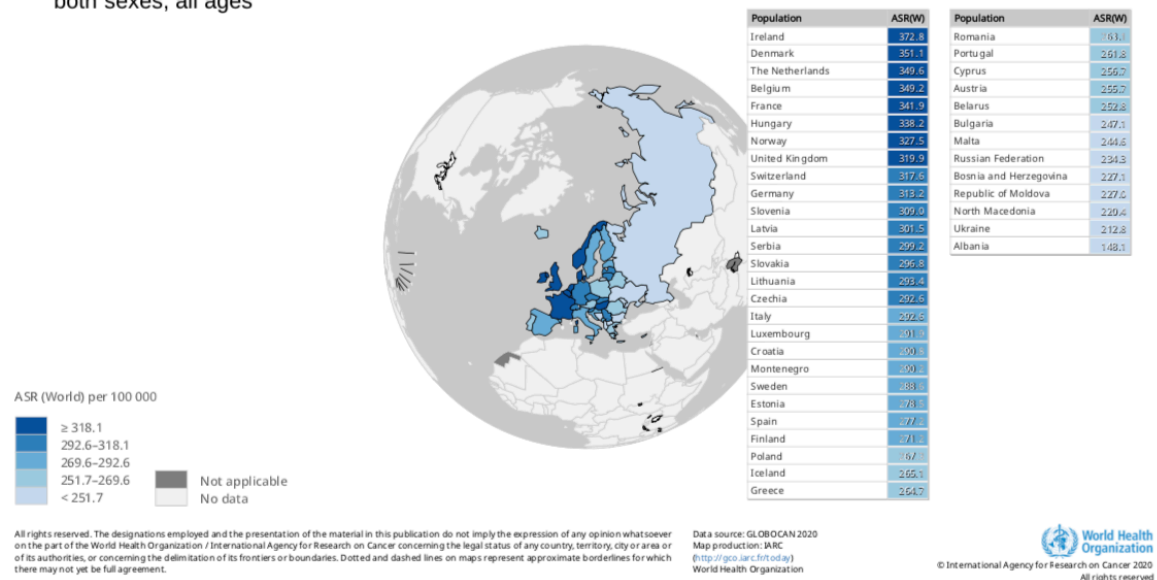


Figure 1: *Incidence rates (world): showing population and figures.* (International Agency for Research on Cancer 2020).

Estimated age-standardized mortality rates (World) in 2020, all cancers, both sexes, all ages

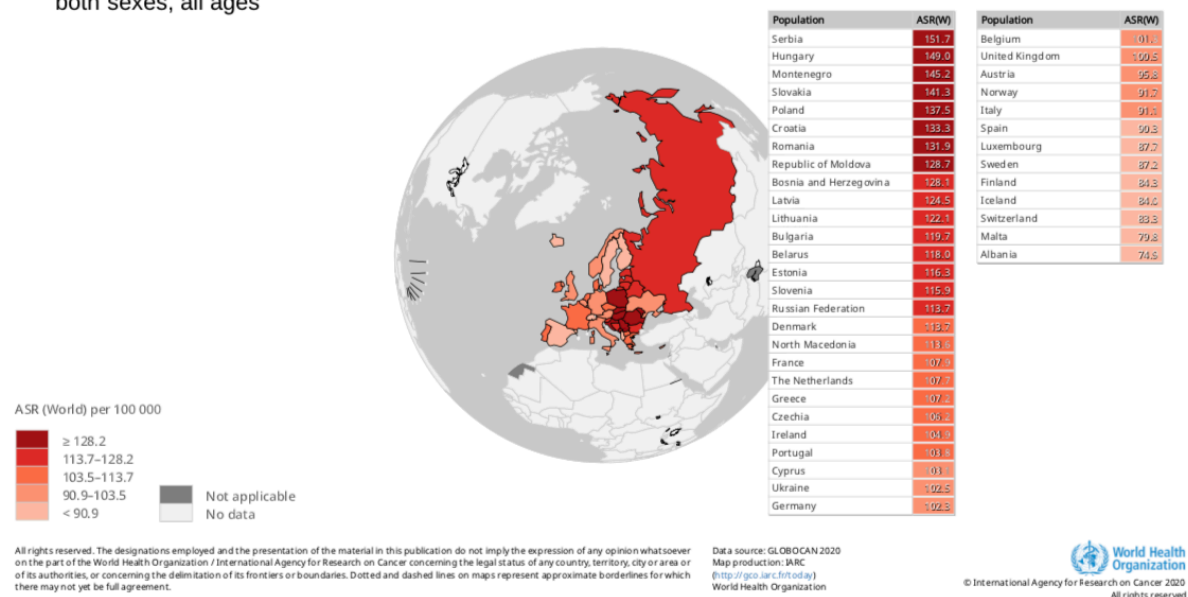


Figure 2: *Mortality rates (world): showing population and figures.* (International Agency for Research on Cancer 2020).

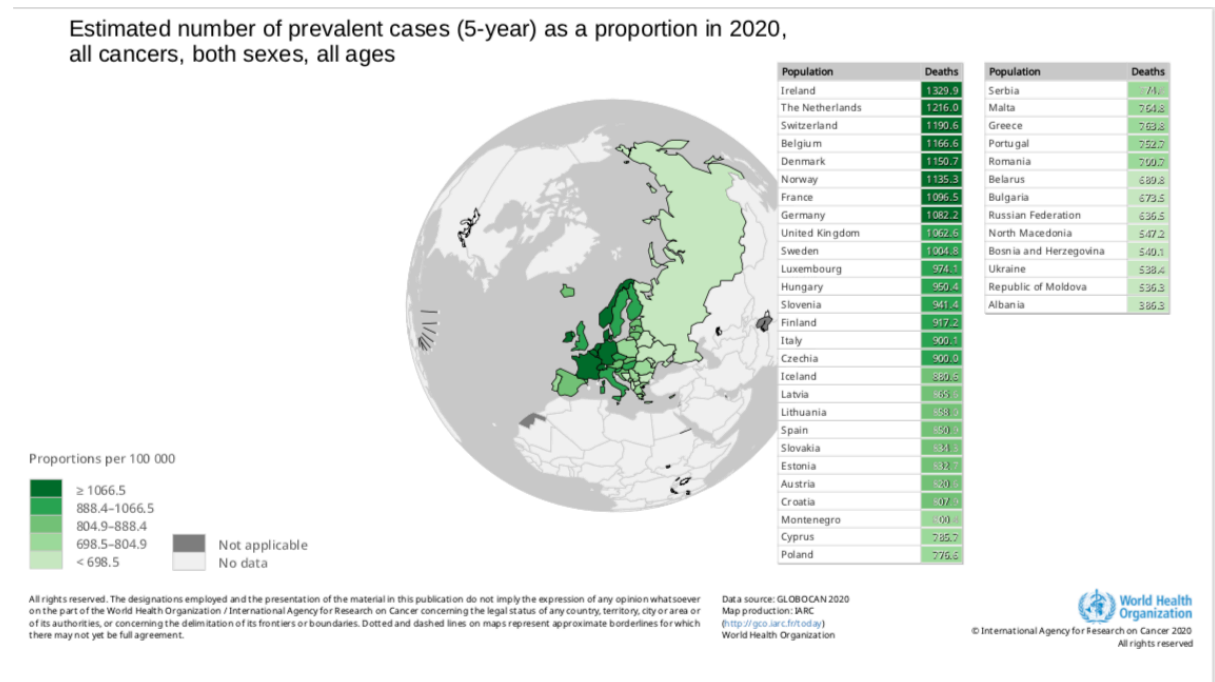


Figure 3: *Prevalence rates (world): showing population and figures* (International Agency for Research on Cancer 2020).

Chapter 1 Introduction

1.1 Introduction

This chapter provides the context to this systematic review, which investigates the clinical evidence-base for massage and foot reflexology. This includes; epidemiology; background and statistics; definitions of complementary and alternative medicine (CAM) as an umbrella term; palliative care & cancer survivorship; CAM utilisation; use of CAM; medical acceptance of CAM; integrative oncology; evidence-based medicine & whole-system approaches; health-related quality of life (HQoL) & well-being. The chapter concludes with a summary description of massage and reflexology, the history with their associated benefits.

While complementary and alternative medicine (CAM) may offer solutions to alleviate healthcare economically there is growing concern about the prioritisation of the cancer survivorship population across the globe. Turning attention to cancer survivors means significant investment. However challenging, research that supports patients on the cancer trajectory is not just an interesting subject, but a worthwhile one which can potentially increase quality of life for many, enabling people from all cultures to live *beyond* cancer. The adoption of Integrative Oncology including modalities such as massage and reflexology into routine clinical care of cancer patients is an important development in current oncology practice (Alain 2021). These developments in cancer care and survivorship represent a significant paradigm shift in healthcare delivery.

1.2 Epidemiology

Cancer is a public health problem, threatening millions of people around the world, disproportionately affecting many countries in Asia, followed by central and eastern Europe. A very clear comparison and relationship can be seen visually between high mortality (death) rates in the east versus high prevalence (survivor population) in the west. The decline in mortality rates in high income countries can be attributed to improvements in cancer prevention, diagnosis and treatment (Sanctucci 2020). Part

of this trend includes attention to health-related quality of life, mental health & wellbeing (Singer 2010; Wanchai 2020).

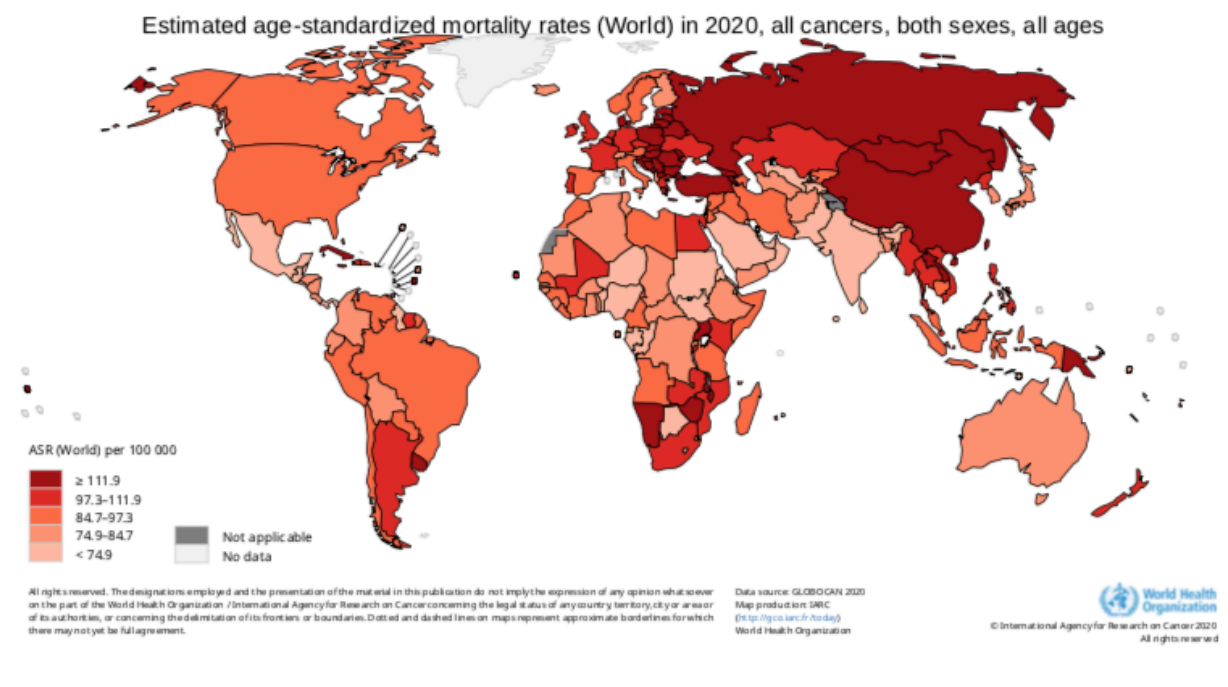


Figure 4: *Estimated world mortality* (International Agency for Research on Cancer 2020).

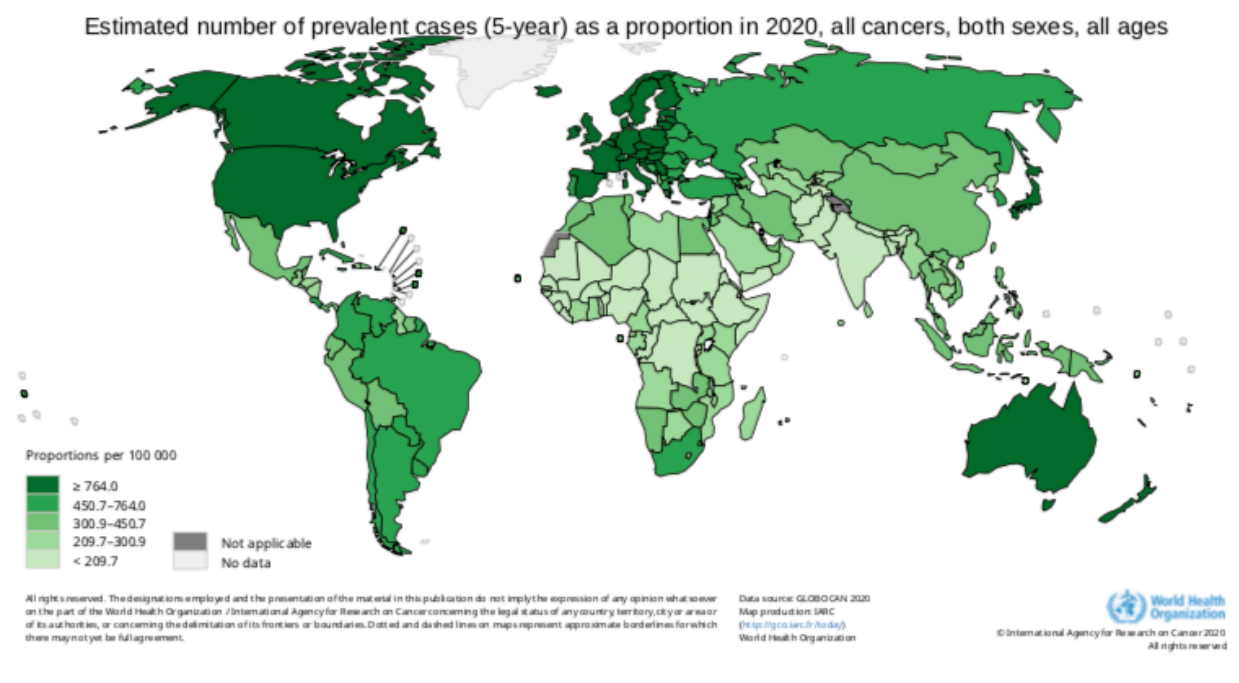


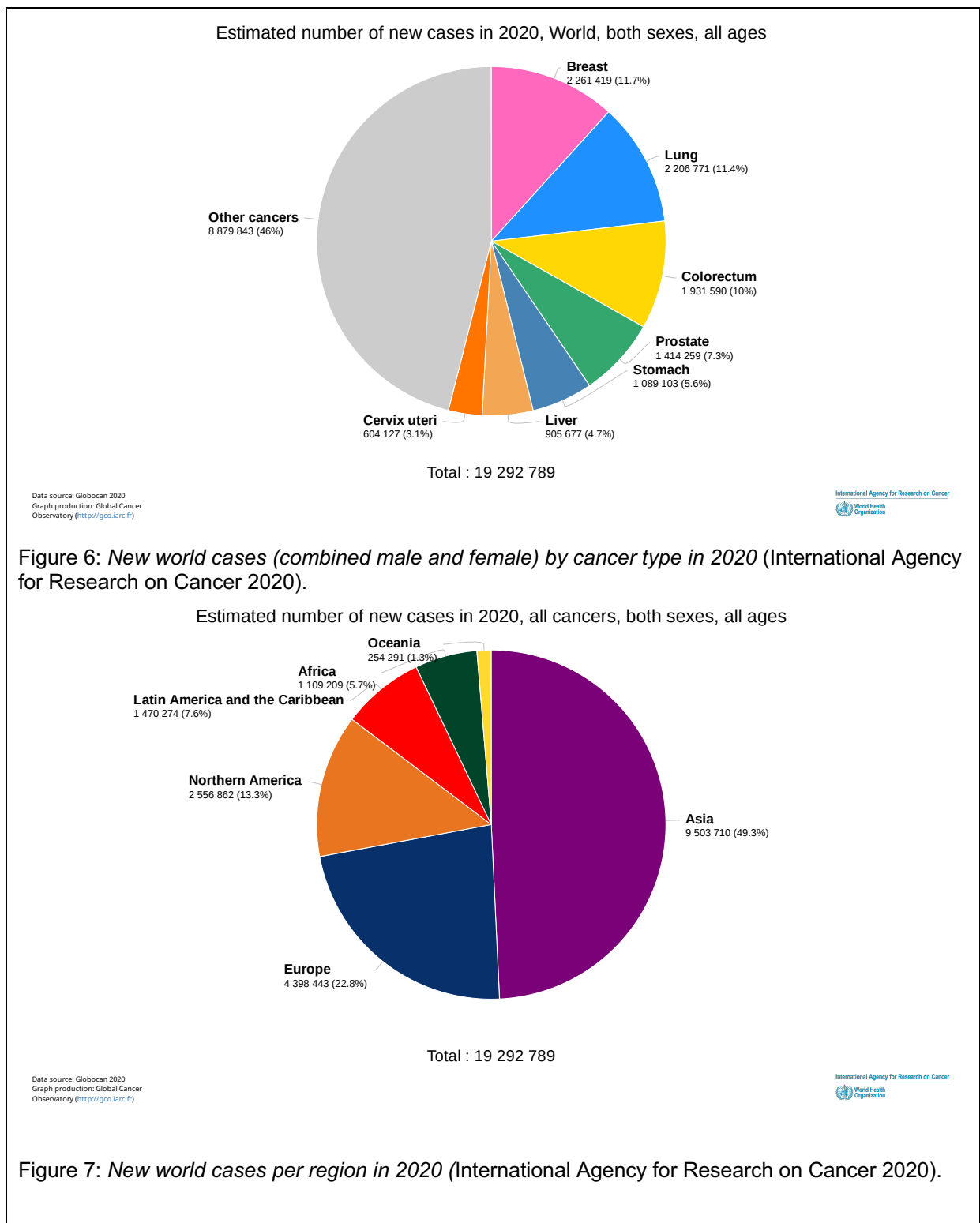
Figure 5: *Estimated world prevalence* (International Agency for Research on Cancer 2020).

1.3 Background

In 2020, the International Agency for Research on Cancer estimated new cases globally were to be 19.2 million. Across Europe this was estimated to include 4.4 million new cases, with the UK estimating to have 458,000 new cases (International Agency for Research on Cancer 2020). Ferlay (2021) concurred with this, expecting a 50% increase in new cancer cases in the next twenty years . Similarly, Jun (2021) wrote that the increase in cancer incidence and mortality is challenging cancer care delivery globally, disproportionately affecting low and middle-income countries (LMIC's) when it comes to receiving evidence-based cancer, prevention, treatment and palliative survivorship care.

Cancer Today provides a suite of data visualisation tools to explore estimates of the incidence, mortality and prevalence of 36 specific cancer types and of all cancer sites combined in 185 countries of the world in 2020 by sex and age group. As highlighted by Cancer Today (2020), caution should be exerted when looking at estimates because of the limited quality and coverage of cancer data particularly in low and middle-income countries. Part of the ongoing analysis of global cancer data and the elucidation of cancer occurrence worldwide is the use of terminology including *incidence, mortality and prevalence* of cancer. Incidence is the number of new cases arising in a specified population over a period of time. Cancer Today (2020) tells us the cancer incidence rate provides the *average* risk of developing a cancer. While mortality signifies the number of *deaths* due to cancer occurring within a specified population over a given period of time (typically 1 year). Prevalence is the number of individuals within a *defined population* who have been diagnosed with and who are still alive at any given point in time. This essentially refers to the survivor population. 'Complete prevalence' is the number of individuals alive, who have been diagnosed with the disease of interest regardless of time passed; 'partial prevalence' limits the number of patients to those diagnosed within a defined period of time in the past and is used to measure cancer burden in populations (Cancer Today 2020).

As the following charts show, incidence of types of cancer differs globally, as does cancer mortality (Sung 2021). This format further clarifies the estimates:



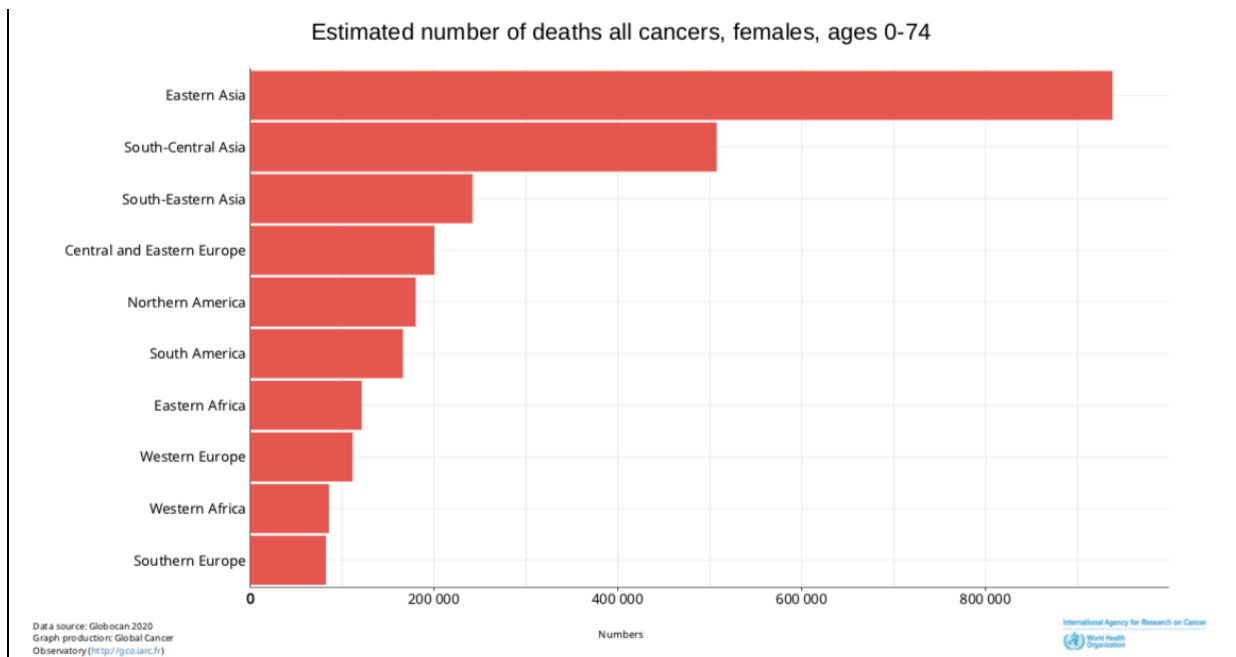


Figure 8: *Global mortality statistics for females in 2020* (International Agency for Research on cancer 2020).

The overall picture is more nuanced in terms of cancer types as per figure 10 where breast cancer presents as the highest incidence in terms of cancer types followed by prostate in men:

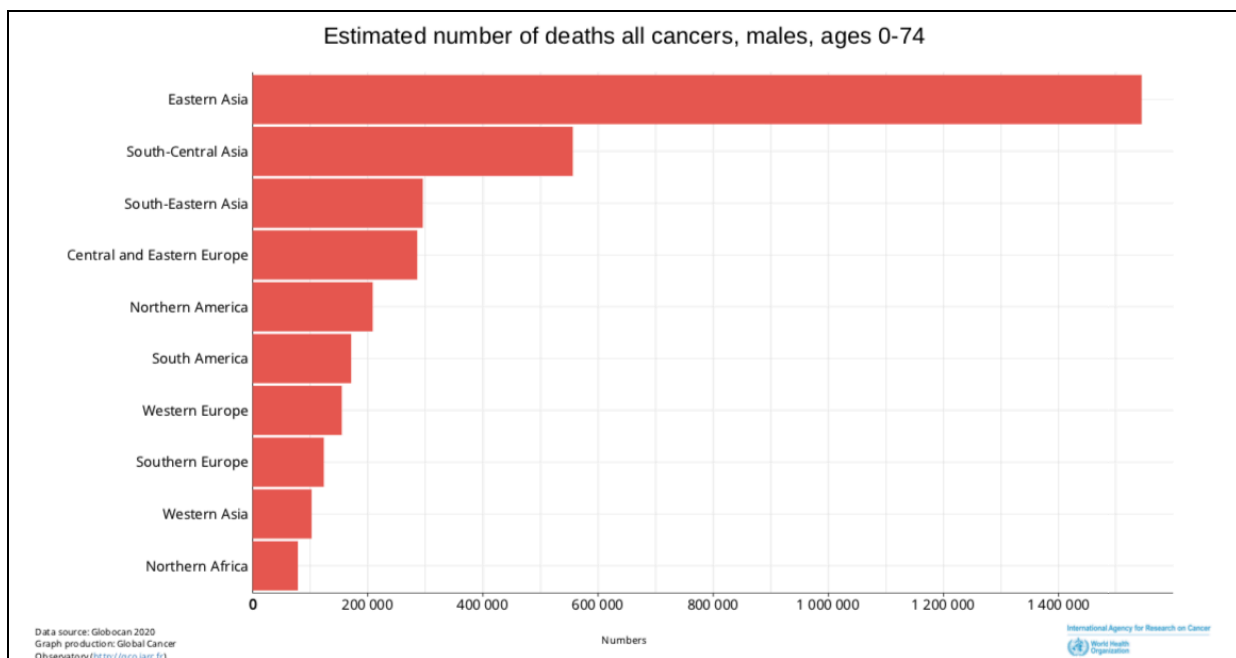
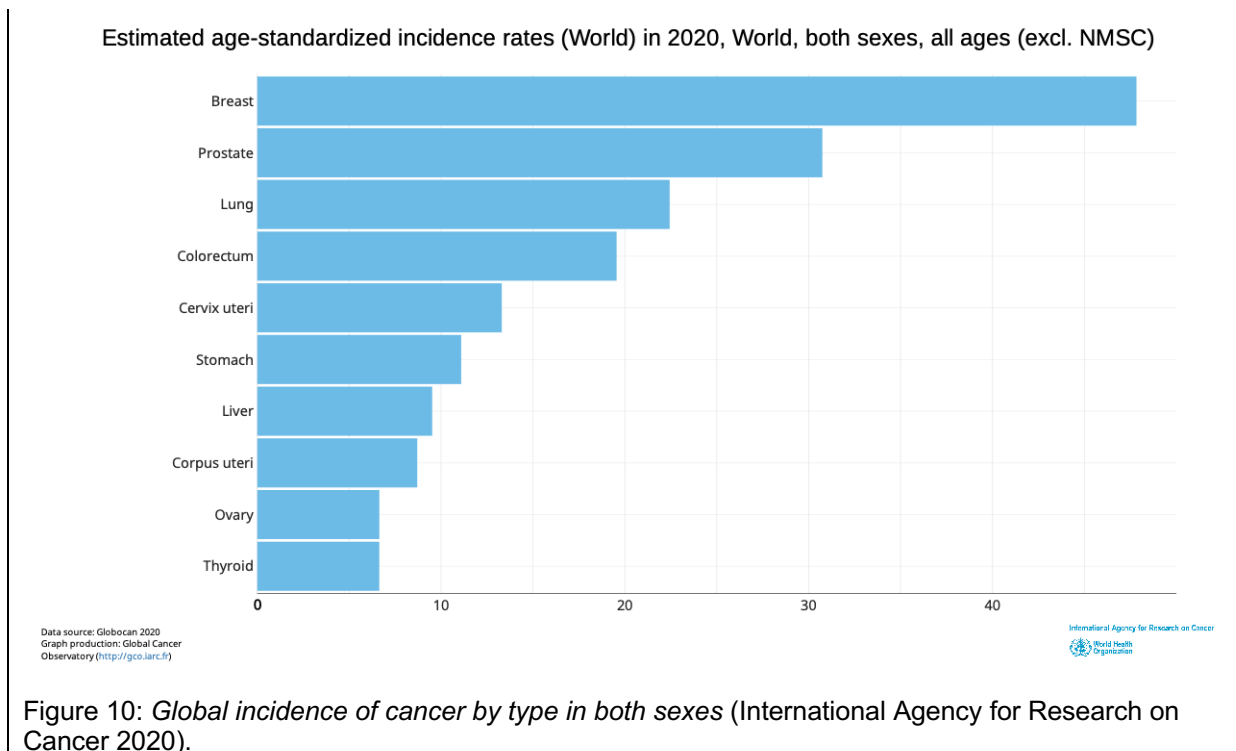


Figure 9: *Global mortality statistics for males in 2020* (International Agency for Research on Cancer 2020).



The approximated global incidence within the sexes combined shows the average *risk* of developing cancer is significant for both sexes in 2020. While this provides epidemiological information about cancer research, with attention turning to quality of life and cancer survivorship, it is also imperative to understand more about cancer prevalence. Geerse (2018) tells us that to date, the majority of research has focused on breast cancer, whereas research is lacking in cancers with similar survival rates.

1.4 Definitions of Complementary & Alternative Therapy (CAM/TCAM)

Calcagni & Quitard (2019) explain that lack of clarity and evolving definitions of CAM is problematic for researchers. Commonly used therapies including reflexology, osteopathy, or chiropractic care are coming under the interchangeable terms of ‘manipulative and body-based practices’ or ‘manual body-based therapies’. Likewise, Cai (2023) writes that CAM can be divided into four types of treatment: 1) traditional Asian medical systems (TAMS) including traditional Chinese medicine, acupuncture and acupressure; 2) alternative medicinal systems (AMS) including homeopathy and herbal therapy; 3) manual body-based therapies (MBBTs) including massage therapy, chiropractic therapy, osteopathy and reflexology; and 4) mind-body therapies including hypnotherapy and psychotherapy (Bodeker 2005 & Kemppainen 2018). Traditional

Complementary and Alternative Medicine (TCAM) is also synonymous with CAM (Peltzer & Pengpid 2018). The category of particular importance for this review is ‘Mind & Body Practices’ because massage & reflexology are used within Integrative Oncology (IO).

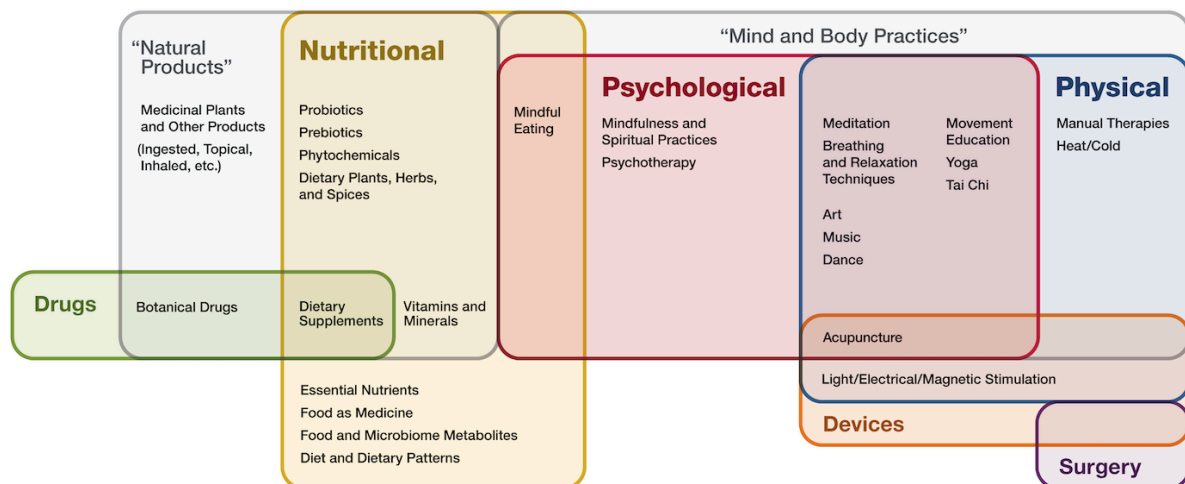


Figure 11: *Illustrative examples of therapeutic input framework* (National Centre for Complementary and Integrative health 2023).

1.5 Palliative Care & Cancer Survivorship

The terms ‘survivorship care’ and ‘palliative care’ are both associated with uncertainty regarding who provides the care and what it entails, and although they sound paradoxical they have a lot in common (Geerse 2018). Varying use and interpretations of the definitions confuse clinicians and patients (Geerse 2018). However, shared strategies may foster advances in both fields, in terms of delivery of high-quality patient care. Contrary to the appearance of a unification of people under one umbrella term, cancer survivors are an extremely diverse group with varying needs due to a number of factors including: a) cancer type, b) stage of diagnosis, c) age at first diagnosis, d) racial differences and disparities and e) anti-cancer treatment (Nakandi 2023). Gentile (2020) says that the consideration of mental health and wellbeing during and after cancer treatment is an important factor throughout the disease trajectory.

The number of cancer survivors is increasing across Europe requiring more intensive research into this cancer population (Blickle 2024). Frequently reported sequelae in

the aftermath of cancer are fatigue, depression, cognitive impairment, distress and reduced quality of life (Lagergren 2019). Fatigue is one of the most reported sequelae and future studies should aim for a better understanding of the mechanisms leading to post-traumatic growth. While Bickle (2024) states that no studies exist that analyse the influence of pain on post-traumatic growth, although it is plausible that pain could have an adverse impact on wellbeing and coping in survivorship stages.

Levit (2013) writes about a multimodal approach and the necessity of expanding the role of health care providers without speciality training in oncology or palliative care. This can be seen in the diagram of shared and actionable steps below where enhancement of the workforce, cost-effectiveness models of care delivery and implementation of quality metrics are needed.

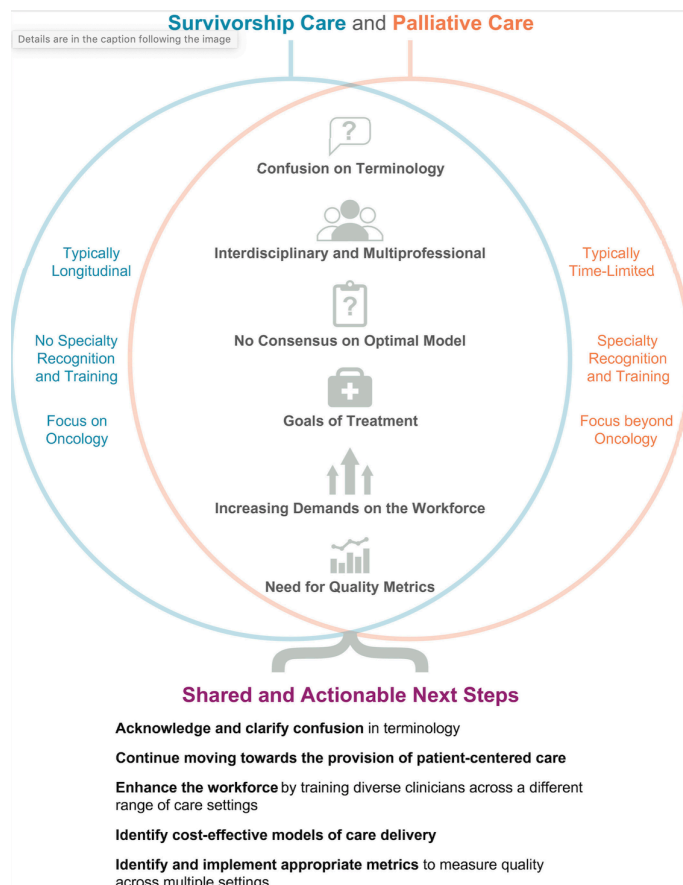


Figure 12: Venn diagram. Illustrating shared opportunities for collaborative learning & actionable next steps for the fields of survivorship care & palliative care (Geerse 2018).

1.6 CAM utilisation among Cancer Survivors

Nakandi (2023) reports that the prevalence of CAM utilisation among cancer survivors varies from country to country from 16.5% in Italy to 93.4% in China (Buckner 2018 & Keene 2019). While in Scandinavian countries like Sweden and Denmark prevalence of CAM utilization ranges from 34-49% (Wode 2019).

A recent Norwegian study exploring the rationale for CAM use among cancer survivors found that most survivors used CAM to increase quality of life & wellbeing (Kristoffersen 2022). What is more, short-term (female) survivors were more likely to use CAM than those less than a year (acute survivors) and more than 5 years post-diagnosis (long-term survivors). Similarly, a study in US found the same trend with short-term cancer survivors using it more than long-term survivors (Fjaer 2020).

Correspondingly, Balneaves (2022) writes that the specific reasons for using CAM reported by those living with cancer include; managing treatment-related symptoms and side-effects (Ku 2012); improving quality of life (King 2015); providing a sense of control (Truant 1999); boosting the immune system (Yildirim 2010); fighting the disease (Evans 2007); preventing recurrence or a 'last resort' (Evans 2007).

1.6.1 Use of Complementary & Alternative Therapy (CAM/TCAM)

In 2018 the World Health Organization reported that the prevalence of CAM usage in the European region, region of Americas and Western Pacific region in 2018 was 89%, 80% and 95% respectively (World Health Organization 2019). By contrast, the review by Phutrakool & Pongpirul (2022) found the corresponding prevalence was 54%, 59% and 37% respectively. In terms of economic level of the countries investigated, there was a higher prevalence of CAM use in the upper-middle economies than the high-income economies. It might be argued that this could be attributed to cultural & historical influences as well as the implementation of CAM in the national health service as seen in Brazil & Mexico (Samano 2005 & Sawni 2007). This is similar to another review by Harris (2012) which revealed that the highest prevalence of CAM provider use (over 50.0%) in East Asian countries (China, the Philippines and Republic of Korea). The assumption could be made that the high prevalence of CAM use in East Asia areas could be attributed to institutional acceptance of CAM. For example, 'unification' in China; 'equalization' in Korea and 'subjugation' in Japan (Calcagni & Quintard 2019).

In terms of the research, there is a significant imbalance which requires to be addressed. It should be noted that country CAM provider use prevalence estimates are difficult to compare with previous surveys since different measures and methods may have been used, so caution should be exerted when coming to conclusions (Harris 2012).

1.6.2 Medical Specialist's Acceptance of CAM

The acceptance of CAM and use within the medical specialists have been inconclusive. A 2022 systematic review shows how CAM seems to be accepted most by family medicine but the least by surgery specialties as can be seen from the diagram below: Family Medicine reported the highest acceptance, followed by Psychiatry and Neurology, Neurological Surgery, Obstetrics and Gynecology, Pediatrics, Anesthesiology, Physical Medicine and Rehabilitation, Internal Medicine, and Surgery. The overall use of CAM was 45% (Phutrakool & Pangipul 2022).

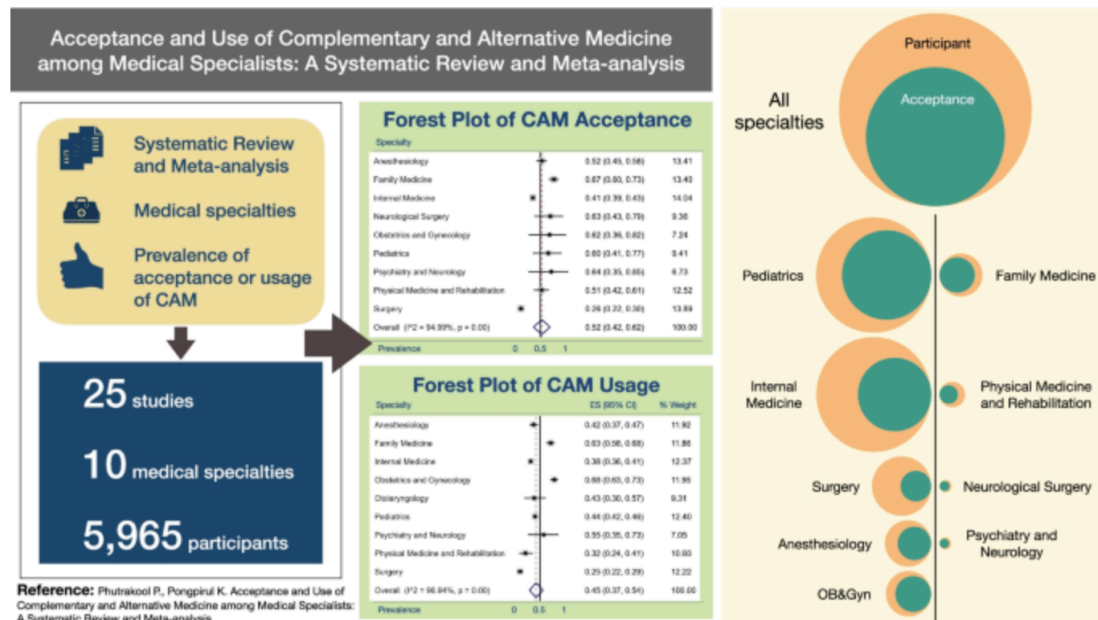


Figure 13: Acceptance & Use of CAM among Medical Specialists. (Phutrakool & Pongpirul 2022).

The highest difference of prevalence was in the field of Physical Medicine and Rehabilitation (19%). In fact, nearly two-thirds of the rehabilitation physicians advised against the use of CAM as a therapeutic option (Sawni 2007). Indeed, some doctors

are sceptical of CAM because of the lack of specific knowledge and qualifications as well as a lack of evidence from high quality experimental studies on the efficacy of CAM treatments (Phutrakool & Pongirul 2022). The reservations are understandable from a medical perspective and indeed, some research has shown poor outcomes for patients who refused standard treatment (Kurian 2012). The reality is that better understanding of how various medical specialists perceive of CAM is strategically essential for harmonizing CAM into conventional medical practices.

1.7 Mental Health

Smith (2018) tells us that the somatic presentations of depression, including fatigue, loss of appetite, weight change and poor cognition can be dismissed by clinicians simply as symptoms of cancer or side effects of treatment which leads to decreased detection of the disorder. A meta-analysis revealed that minor or major depression increases mortality rates by up to 39% and that patients displaying even few depressive symptoms may be at 25% increased risk of mortality (Satin 2009).

Interestingly, according to Linden (2012) the site of primary cancer influences the rates of depression, with depression being most common in pancreatic and lung cancers and lowest in invasive skin cancers. Age influences prevalence of depression while gender is a significant factor; in some cancers, patients were found to be two to three times more likely to experience depression than males (Linden 2012). While levels of psychological stress may vary over the course of the disease, and are highest around the time of diagnosis, depression in cancer survivors five years following diagnosis are comparable to the broader public at 4% (Boyes 2009).

Finally, metastasis and cancer pain have been associated with higher levels of depression (Ciaramella & Poli 2011). There is suggestion in the literature that pain may be the causative factor in depression. The relationship between depression and pain is very relevant to the question this systematic review poses, but is outside the scope of this review. It should be noted that many studies have found that massage can reduce muscle fatigue, improve blood flow, relax mood, and relieve cancer symptoms such as anxiety, depression, pain and nausea (Smith 2015); and relief of anxiety and depression in cancer survivors (Wilkinson 2008).

1.8 Evidence-based Medicine & Whole-systems Approach (WSA)

Latte-Naor (2022) writes that a key feature which distinguishes integrative oncology from alternative medicine is its foundation of evidence-based practice. As a concept, it has transformed medical education and clinical practice. Researchers from multiple fields in TCIM have critiqued the randomized-controlled trials (RCTs) limitations and its disproportionate evidentiary dominance. Alternatively, 'whole systems approach' research (WSR) approach often evaluating multimodal CIM therapies and their impact on often self-reported patient outcomes, offers a pragmatic alternative to conventional clinical study design for CIM therapies (Ijaz 2019). Currently securing funding to conduct innovative whole-systems approach studies is a prominent challenge (Rittenbough 2010).

1.9 History of Foot Reflexology

Reflexology is an ancient practice with an interesting history evolution from many cultures and traditions to the modern practice that exists today (Hart 2015). Reflexology was used by the Chinese, Egyptians and North Americans indigenous tribes for healing. Two internationally recognised reflexology methods are the Ingham method and the Rwo Shur method. It was not until the 19th century that the medical community, nursing, complementary and alternative medicine (CAM) practitioners began to explore it scientifically (Cai 2023). Reflexology has grown into a complex therapeutic modality which is reported anecdotally to have a range of effects (Whatley 2023).

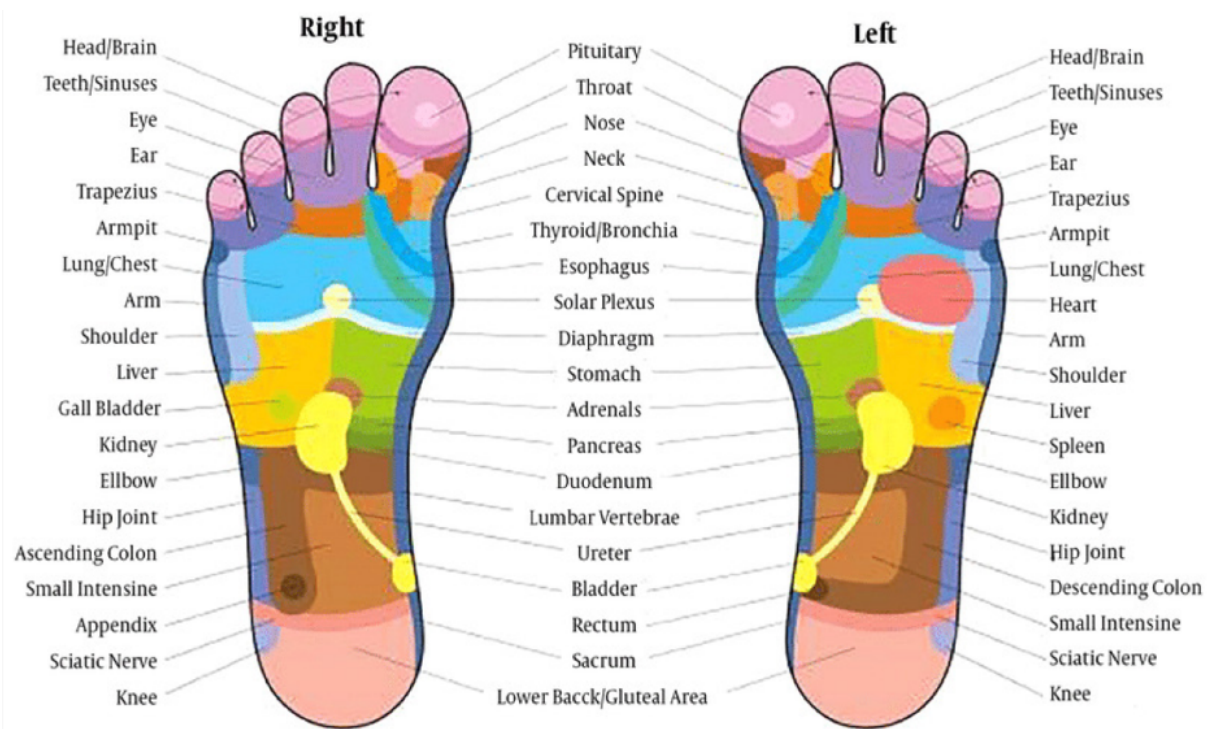


Figure 14: *Foot reflexology chart* (Deng-Chuan 2022).

As can be seen, reflexologists work with the concept that the sole of the foot is a map which represents the whole body.

1.9.1 Is Reflexology the same as Massage?

A leading researcher in the field, Wyatt stated that reflexology is more like acupuncture or acupressure than massage (Wyatt 2022 cited by Hart 2015, p.121) Likewise, Smith (2018) writes that the application of pressure to specific, superficial points renders it different from massage modalities. Along the lines of differentiating massage and reflexology, there is an interesting body of work on 'affective touch'. In the 1990s it was discovered that there is a sensory nerve that responds to pleasant touch called 'C-fibre'. Furthermore, there are two types of skin: 1) *glabrous skin*; palms of hands and soles of feet & 2) *hairy skin*; which is on the rest of the body. The C-nerve fibre that responds to stroke the neurological basis for 'affective touch' on hairy skin only (McGlone 2018). The presence of this nerve fibre in hairy skin only has implications for the research mechanisms of action in massage and reflexology; manipulations of

a stroking nature used in massage may in fact have different physiological effects to the 'on/off' pressure exerted in reflexology (McGlone 2018).

1.9.2 Benefits of Reflexology

Cai (2022) report in their bibliometric analysis spanning 31 years (1991 - 2021) that reflexology has been shown to be useful for a myriad of different problems including: headache pain, back pain, joint pain, caesarean pain, acute pain in infants, pregnancy pain, labour pain, oedema in pregnancy, various cancer pains, musculoskeletal cases as well as a treatment for strokes, insomnia, asthma, diabetes, multiple sclerosis. In the same way, McCullough (2014) shows that reflexology studies have demonstrated beneficial effects on pain, mental health, quality of life and stress. Field (2016) writes that massage therapy is noted to significantly reduce cancer pain as compared to no massage control conditions. Moreover, massage was effective especially for surgery-related pain and among the various types of massage, foot reflexology was *most* effective. Finally, there are many studies exploring reflexology on the quality of life with cancer and the use of reflexology in hospices to alleviate pain at end of life (Zeng 2018).

1.9.3 What is Massage?

Samuel (2021) writes that clinical massage refers to the use of manual manipulation of the soft tissues to relieve specific complaints of pain and dysfunction. Common techniques used may include effleurage, petrissage, percussion, myofascial release, trigger point therapy, deep transverse friction, compression massage and cross-fibre massage. Essentially, massage highlights a method of manipulating the soft tissues of the body using pressure and traction to enhance function, decrease muscle reflex activity, inhibit motor-neurone excitability, aid the healing process and promote relaxation and wellbeing (Lee 2011).

1.9.4 History of Massage

The history of massage can be traced back thousands of years to ancient China, India and Egypt during the second century BCE; it is one of the oldest healing arts offering

a drug-free, non-invasive and humanistic approach (Pan 2014). Interestingly, Chinese massage combined with herbal ointment is one of the centuries-old complementary and alternative therapies for improving pain, anxiety and muscle stiffness (Lee 2011).

1.9.5 Benefits of Massage

Swedish massage is more commonly used for relaxation while deep tissue massage to relieve pain (Majchrzycki 2014). Specifically, practitioners claim that massage may have several positive effects in the treatment of people suffering from cancer; psychological (reduction of anxiety and depression) or alleviation of physical symptoms associated with cancer and anti-cancer treatments. Many studies have found that massage can reduce muscle fatigue, improve blood flow, relax mood and improve cancer symptoms such as anxiety, depression, pain and nausea (Cassileth 2004; Ernst 2009). Boyd (2016) tells us that in response to a growing demand for holistic pain management approach for cancer patients, therapeutic massage is being used more in medical treatment programs to alleviate pain and related symptoms, as well as enhancing wellbeing.

For example, in studies of women with breast cancer, the quality of sleep, levels of depression, stress catecholamines, immune cells including cytokines (Th1/Th2 immune balance) and natural killer cells have been measured following massage therapy. The results of which suggested that depression and anxious depression were significantly reduced after massage (Krohn 2011). Another breast cancer study reported reduced depression and increased dopamine and serotonin as well as increased natural killer cell number and lymphocytes. It is hypothesised that increased dopamine and serotonin mediated both the decrease in depression and the increased immune support (Field 2014). However, like reflexology, the clinical mechanism of action is still unclear.

According to Rapaport (2018) wider data suggests that massage may decrease problems with depression and anxiety and therefore massage may be a useful adjuvant to conventional care and psychotherapy. Indeed, compared to pharmacotherapy and psychotherapy, massage has unique advantages because of its non-invasive, low-cost and safety characteristics.

Chapter 2 Methodology

2. 1 Introduction

This chapter lays out the research methods employed within the systematic review. The research question is stated, followed by the research aims and objectives which openly acknowledge the need for investment in research to understand how reflexology and massage may work (mechanisms of action). Closely associated, is the section dedicated to the research paradigm(s) which explore philosophical perspectives that feed concurrently into the inquiry. Correspondingly, methodological aspects of the paper are discussed, concluding with ethical principles relevant to systematic review purposes.

2.2 Research Question

In the UK, there is an interest to demonstrate the efficacy and the value of massage and reflexology as adjuvant complementary therapies to conventional cancer care (Candy 2020). While it would appear that complementary & alternative therapies may not have the same potential to save lives or change the course of an illness, nevertheless it affects people's health-related quality of life (HQOL) and like much of general practice, has a highly significant impact on health (Black 2009). The question has a strong utility, but terms such as 'quality of life' which are difficult to operationalize, creating significant challenges in the research process.

Black (2009) writes that there is a paradox at the heart of the noble endeavour to inquire rigorously into how everything works. On the one hand, those of scientific disposition are driven to challenge every hypothesis and view every account or piece of evidence as, as partial. On the other hand, everyone needs confidence in some common accounts of how things work (even when they are incomplete) so that we do not deny ourselves of the undoubted benefits of treatments or technologies, even when our knowledge of their *exact* mechanisms of effect might not be comprehensive. Indeed, as Black (2009) points out, there is often a lack of rigorously proven theory about mechanisms that deliver improved health and is true of many conventional

interventions. This suggests a potential 'shared understanding' between conventional and alternative medicine, rather than polarised positions. Black (2009) states that the challenges offer an opportunity for learning that can be applied not just in complementary practice but also in orthodox research and practice.

2.3 Aims & Objectives

Sofaer & Strech (2012) write that a systematic review answers a specific empirical research question which has a set form including reference to the population, the intervention, the comparator or context and the outcomes. The aims and objectives of this systematic review are to answer the question based on the entire literature, or rather what is possible to access, acknowledging limitations where they can be found.

Within the empirical literature base, there are a number of methodological *questions* that exist. For example, there is significant variability in intervention protocols for massage, even within the randomized controlled trials (RCTs) which are considered 'gold standard'. As Charrois (2015) writes although RCTs represent the optimal study design, not all questions can be answered by an RCT, a concern this review highlights. Wang (2021) says that evidence-based therapy protocols with appropriate modality, favourable duration and frequency with adequate sample sizes and appropriate sham massage designs is *yet* to be designed

This critically orientated systematic review recognizes the limitations and embraces a problem-solving mode of inquiry. The search aims to be reproducible, with the wider purpose of improving decisions that are maximally informed and minimally biased.

2.4 Research Paradigm(s)

According to Dewy's philosophical stance (1931) embedded in epistemology, 'inquiry' is the controlled transformation of a problematic situation. Therefore, the purpose of inquiry is to create knowledge in the interest of change and improvement (Goldkhul 2012). The 'philosophical way of thinking' in terms of paradigms is embedded and referred to throughout the dissertation as a vehicle for potential change. It could be argued that the pragmatic paradigm is relevant because it advocates 'workability' in

the research and a rejection of the need to locate study into one specific paradigm. At the same time, the principles of traditional paradigms of post-positivist and the interpretivist/constructivist paradigm are instrumental in navigating and confronting the issues around the current evidence-base. Rather than two different ontological and epistemological schools of thought, the pragmatist focuses on the two different approaches to the inquiry.

This systematic review acknowledges the pros and cons of the current methodologies in use within massage and reflexology. At the same time, suggestions are made to integrate new adaptable methodologies which are more capable of answering the question. This reflects the dual approach characteristic of pragmatism.

2.4.1 Complex Interventions

Petticrew (2011) addresses the question of what constitutes 'complex' interventions versus 'simple'; complex interventions are non-standard, having different forms in different contexts and concludes that definitions are important because they have direct implications for the sorts of evaluative research. For example, if researchers see 'simplicity' in an intervention they then may be more likely to argue that randomized controlled trials are feasible and appropriate (as opposed to other types of research). However, if they see complexity (non-linear pathways, multiple synergistic components, feedback loops) as the key features, then by implication other types of research may be necessary for illuminating those complex processes.

2.4.2 Positivist & Post-positivist Paradigm

Kivunja & Kuyini (2017) tell us the positivist paradigm is grounded in the scientific method of investigation, with a focus on randomized control studies (RCTs). The paradigm aims to provide explanations and make predictions based on measurable outcomes. Inherent in the positivist paradigm is the belief that we can gain knowledge through mainly quantitative methods which helps us to be more objective in understanding the world around us (Putman 2012; Searle 2015). The 'sister' post-positivist paradigm accepts that truth is not absolute, because the nature of reality in terms of the social world, is far from perfect (Kivunja & Kuyini 2017). The post-positivist

paradigm has a place in evidence-based practice within CAM because of the emphasis on accountability of the researcher and reliability of findings.

The heterogeneity and inherent challenges to validity within studies in this systematic review is evidence of the post-positivist paradigm. The practice of complementary therapies treatment effects at whole-person level (physical, emotional, mental and spiritual) presents opportunities to researchers and therapists to build a stronger research culture, based on more qualitative data.

2.4.3 Constructivist/Interpretivist Paradigm

At the other end of the paradigm continuum is the constructivist/interpretivist paradigm, typically associated with qualitative methods (Kaushik & Walsh 2019). In effect, theory follows research, not precedes it (Kivunja & Kiyuni 2017). Knowledge is being constructed socially including the interaction, experiences and history of the researcher; and that there are multiple realities co-existing to be explored and can be done so through various methods (Chalmers 2005). However, generalizability within the interpretivist paradigm is practically impossible, because by definition interpretivist research is context-specific and cause & effect are mutually interdependent (Gomm 2000). In the placebo effect for example, there may well be a number of active and effective therapeutic actions that we are not yet able to fully describe, recognise and apply in practice (Black 2009). Constructivist/Interpretivist inquiry into the nature of the 'therapeutic relationship' may help determine the evidence-base of massage and foot reflexology within integrated oncology.

2.4.4 Pragmatic Paradigm

Pragmatism rejects the need to locate studies into either a positivist (post-positivist) or interpretivist paradigm. The word pragmatism is originally derived from the Greek word '*pragma*' meaning action and which is the central concept of pluralistic pragmatism (Pansiri 2005). Indeed, practically-minded researchers adopt this method of inquiry (Crewell & Clark 2011). Cresswell (2013) tells us that pragmatism claims to bridge the gap between the scientific method and the structuralist orientation of older approaches and the naturalistic methods of newer approaches. Research methods

are determined by the *purpose* of the research reflecting the ‘workability’ of the paradigm to find ways which allow the researcher to address the question, without the need to fit into either a quantitative or a qualitative domain. Arguably, the most significant feature of the pragmatic paradigm is the *value-laden axiology*, which emphasises conducting research that benefits people (social justice).


2.5 Research Methodology

Morgan (2007) infers that it is important to focus on methodology as a tool to connect our thoughts about the nature of knowledge from our efforts to produce it rather than separating philosophical threads from the research design. The heterogeneity of CAM in which massage and reflexology belong to requires careful consideration and careful inquiry, to deduce with confidence the efficacy and effectiveness of massage and foot reflexology. To mitigate against a misleading or irrelevant outcome in the review, care will be taken to use recognised protocols to assist at all stages of the review process. It can be noted that broad reviews with diverse studies, provide opportunity to ask interesting questions about the *reasons* for differential interventions and effects Higgins & Thomas (2019).

New and emerging research in psycho-oncology, osteopathy in relation to fascia and ‘contextual factors’ are in their infancy and many questions remain to be investigated. For example, researchers from different methodological disciplines are encouraged to explore the knowledge and awareness of contextual factors among practicing osteopaths, students, educators and patients. Quantitative and qualitative study designs can capture views and generate rich data from different perspectives and should incorporate deontological topics such as ethics and communication with patients (Thompson & Rossetini 2021).

2.5.1 PRISMA & Cochrane Collaboration


Malik (2014) writes that conceptual coherence is supported through resources which promote quality, transparency and standardization of reviews.



PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria; participants; and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: www.prisma-statement.org.

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Fig 15. *PRISMA Checklist* (Research Guides No Date).

The Cochrane review of the Cochrane Collaboration; Prospero, was launched in 2011, and PRISMA (Preferred reporting items of systematic reviews and meta-analysis,

2009). Shamseer (2015) states that without review protocols how can we be assured that decisions made during the research process are not arbitrary or that the decision to include/exclude studies/data in a review are not in light of knowledge gained about individual studies. The PRISMA checklist is a minimum set of items for reporting systematic reviews of healthcare interventions to mitigate against undermining the review. Aveyard (2021, p75) tells us that PICO provides the most comprehensive range of results by focusing the search on four key areas:



Fig 16: *PICOS acronym* (Centre for Reviews & Dissemination 2008).

These elements of the review question, together with the study design will be defined in order to determine the specific inclusion criteria that will be used when selecting studies for the review (Centre for Reviews & Dissemination 2008). In fact, the PICO construct can be used at different stages of the review process; review PICO (eligibility of studies); PICO for each synthesis (defining the question that each specific synthesis aims to answer); PICO of included studies (what was actually investigated in the included studies (Higgins & Thomas 2019). Following this process within a systematic review allows the author to state how confidently we should accept the answer to the question and if the question is *not* settled, then further research is needed (Sofaer & Strech (2012).

Population	Cancer patients & survivor populations
Interventions	Massage & foot reflexology.
Comparators/Context	Comparators: Any control that is compared to massage or reflexology. Context: various oncology sites ie Hospital and others.
Outcomes	Health-related Quality of Life/Cancer symptom management including: pain, peripheral neuropathy, insomnia, anxiety & depression (mental health). The list is not exhaustive.
Study Design	Primarily randomized control trial (RCTs). Consideration/justification of other methods lower down on hierarchy including; naturalist experimental (explanatory and pragmatic) phenomenology, causal comparative methodologies.

Figure 17: *PICO construct to help answer the question posed by the systematic review.*

Where comparative studies are included, the protocol should specify which comparators are eligible, so the scope of terms is clear (Centre for Reviews & Dissemination 2008). Garlehner (2006) writes that efficacy trials (explanatory trials) determine whether an intervention produces the expected result under ideal circumstances. Effectiveness trials (pragmatic trials) measure the degree of beneficial effect under the 'real world' clinical settings. Distinguishing between efficacy and effectiveness contributes an important aspect to analysing clinical evidence and details on this distinction will be provided in the review of the data. In terms of outcomes, consideration will be given to the timing of outcome assessment and any potential adverse effects. Finally, the types of study included in the review will play a major role in determining the reliability of the results and the validity of estimates effect is linked to study design. While some studies are clearly more robust than others, this should not be the only factor in determining which types of study are eligible for the inclusion (Centre for Reviews & Dissemination 2008). Indeed, pragmatism does not advocate that 'if it works then it's true' (Boisvert 1998) Pragmatists will carefully consider *all* information on the basis of utility, and how it can be best explored while adhering to the relevant protocols to facilitate inquiry.

2.5.2. Inclusion/Exclusion Criteria.

Aveyard (2021, p94) tells us that the first step in identifying relevant papers is to consider the full paper against inclusion/exclusion criteria for assessing suitability and helps clarify understanding of the papers. If for example, effectiveness of a specific intervention is the focus, then any studies that do not compare one treatment option against another or placebo are excluded. Therefore, only randomized control trials that considered effectiveness would be included. Different methods of appraisal may complement RCTs; observational studies (cross sectional, cohort) and pragmatic (real life context of clinic) when assessing unanswered questions by RCTs (Calgagni 2019).

Inclusion criteria – answers to all questions must be ‘yes’.

- Is the publication date from 2012 onwards?
- Is the publication in other languages and not only English language?
- Is the study a Randomized control trial (RCT)? If not, justify.
- Is there an appropriate comparator/placebo/other?
- Is the publication a theoretical paper by an expert in a relevant health area? Justify inclusion ie Psycho-oncology.
- Is the publication peer-reviewed? If not, can you justify its inclusion?
- Is the publication a literature review (systematic, scoping, narrative)? Justify inclusion.
- Does the study focus on massage and/or foot reflexology exclusively?
- Does the publication population include either *cancer patients* or *cancer survivors*?
- Is the study involving cancer patients/cancer survivors focusing on either symptom-management (fatigue, pain, anxiety) or health-related quality of life?
- Is the population considered adult ie over 18yrs of age?
- Is intervention massage and/or reflexology? If aromatherapy is involved, then must be justified.
- Is the intervention delivered in a health care setting (Hospital, Hospice, Integrated Oncology setting).

Exclusion criteria - answers to all questions must be ‘no’

- Is the study dated within a ten year period?
- Does the study have a clear methodology? Justify use if not.
- Does the study have a good sample size? Justify use if not.
- Is the study clear about **ethical** considerations?
- Is the study dealing with cancer only (any type) as opposed to other illness?
- Is the study using inclusive of *all* adults and demographics (gender, culture)?
- Does the study focus on other forms of CAM therapies ie Reiki, acupuncture..
- Is the study involving participants who are have other illnesses such as rheumatoid arthritis, MS, other disabling problems.
- Is the study inclusive of children? (Pediatric oncology)
- Is the setting appropriate for the purposes of the review? (clinical,hospice, hospital, chemo-site, GP practice, nursing facility).

Figure 18: *Inclusion & Exclusion Criteria used to guide systematic review.*

2.5.3 Search Strategy

Aveyard (2014, p91) cautions against only including literature that has been published because of the risk of publication bias, that is journals tend to publish research that shows the positive effect of an intervention rather than a negative or no effect. Massage and reflexology has a strong anecdotal history, so the search for grey literature in various forms is important. A number of grey literature resources found and used for review purposes in retaining a holistic perspective:

Global Health (Ovid)	Health Management Information Centre (HMIC)
OpenDOAR	National Grey Literature Collection
PsychEXTRA (APA)	Social Care Online
OpenAIRE	Social Science Research Network
Best Practice (BMJ)	UpToDate
Semantic Scholar	BASE: Beilefeld Academic Search

Figure 19: Grey Literature Databases.

Cai (2023) shows that in 2020, the top three publishers in Complementary Therapy searches were Elsevier (27.4%) Wiley (11.7%) and Lippincott Williams & Wilkins (6%). What is more, the study found that the number of articles published in the field of foot reflexology has been increasing year by year with the top three journals containing the most articles as follows; *Complementary Therapies in Clinical Practice* accounted for 11.1%; *Therapies in Medicine* (9.6%); *Journal of Alternative and Complementary Medicine* (3.90%); *Cochrane Database of Systematic Reviews* (3.10%). According to statistics, the authors the top key word usage were; *CAM; massage; cancer; fatigue; breast cancer; complementary medicine; pregnancy; multiple sclerosis; constipation; chemotherapy*. The most prolific authors/scholars in the field of reflexology were named as Wyatt, Sikorskii & Victorson, who have carried out extensive collaborations and can be observed in figure 20 and 21 below:

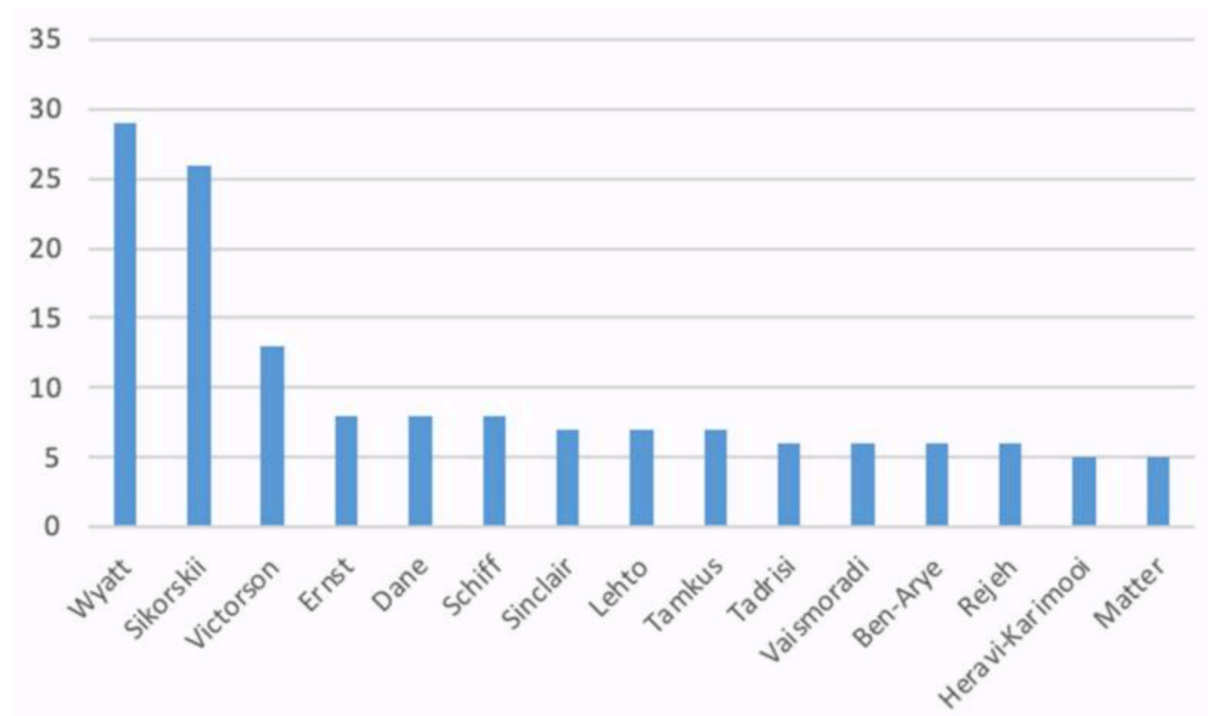


Figure 20. *Author rankings related to reflexology* (Foot Reflexology: Recent Research & Prospects 2023).

Below we can see the ever-expanding collaborative network of prolific authors and research institutions in the field of reflexology research between 1991 and 2021.

Because of this wealth of information, there is a platform on which to begin the inquiry.

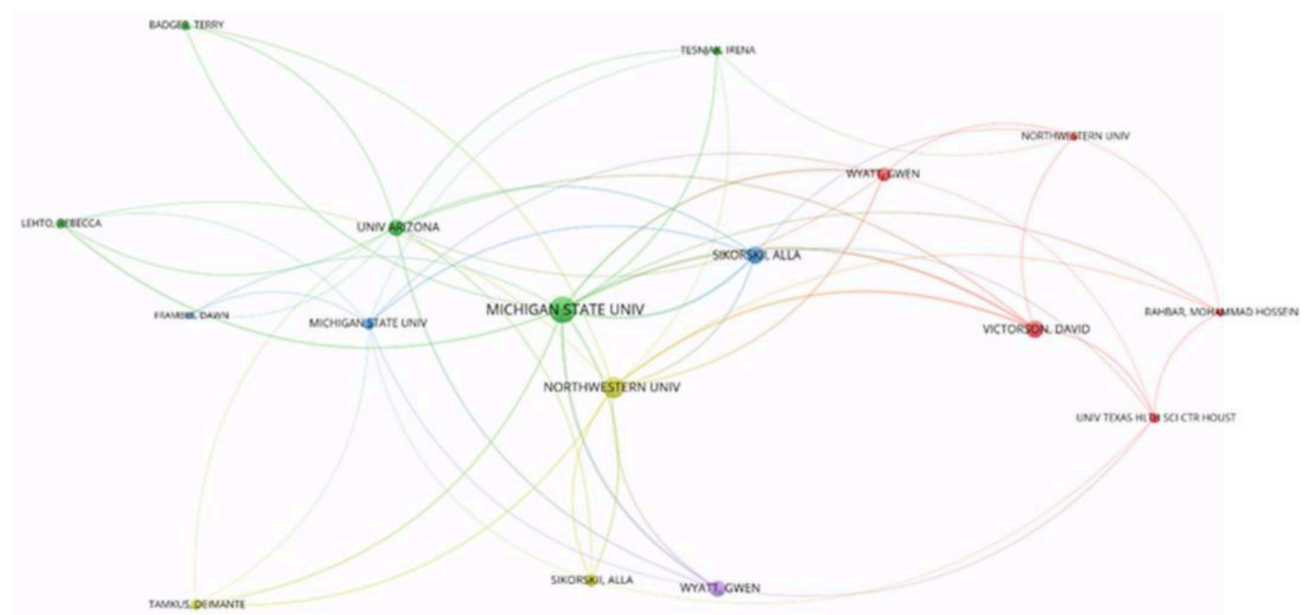


Figure 21: *Collaborative network of prolific researchers & institutions.* (Foot Reflexology: Recent Research & Prospects 2023).


Advice from the University of the Highlands & Islands librarian was sought from the start which began an initial search within the following databases: Scopus; ScienceDirect; Springer; CINAHL; Wiley; Cochrane Library; Embase; Medline; AMED & Nursing & Allied Health (Proquest). Care has been taken to include research from 2012 onwards to the present day. Using 'Advanced search' and making use of the AND/OR/NOT commands which are principles of the Boolean logic and feature of all databases, primary key search words included: complementary therapies; massage; reflexology; cancer; cancer care; side-effects using the 'AND' technique for limiting the search, whilst the use of 'OR' widening the search: Massage AND cancer survivorship; massage AND symptom management; reflexology AND symptom control; benefits of reflexology AND oncology; oncology AND integrative medicine; massage AND oncology AND depression; oncology patients AND comparative effectiveness research. 'NOT' was used to a lesser extent because of the concern of missing out relevant papers. The identification of MeSH terms has been instrumental in generating new potential search terms including: cancer survivorship; psycho-oncology; psycho-social outcomes. Following up 'cited by' and 'similar articles' in a systematic way has also yielded good results. Other on-line resources included: Scite; Absohost; Cam-cancer; NCCIH. More resources can be found in 'Useful Resources'.

2.6 Template for Intervention Description & Replication (TIDieR)

Hoffman (2014) writes that a major part of research activity is evaluation of interventions. However, the quality of descriptions in publications remains remarkably poor. In practice, this has a negative impact on future researcher's ability to replicate, or indeed build on research findings. Intervention description involves more than just providing a label but instead should record the following key features; duration, dose, intensity, mode of delivery, essential processes and monitoring. What is more, for complex (massage and reflexology) this detail is needed for each component of the intervention (Hoffman 2014).

Moreover, the completeness of intervention description is often worse for non-pharmacological interventions; one analysis of trials and reviews found 67% of descriptions of drug administration were adequate compared with only 29% of non-pharmacological (Glasziou 2008). This knowledge can be utilised to generate better

reporting within systematic reviews, highlighting areas of strength and weakness within the literature on massage and reflexology.



The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
1.	BRIEF NAME Provide the name or a phrase that describes the intervention.	_____	_____
2.	WHY Describe any rationale, theory, or goal of the elements essential to the intervention.	_____	_____
3.	WHAT Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	_____	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	_____	_____
5.	WHO PROVIDED For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	_____	_____
6.	HOW Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	_____	_____
7.	WHERE Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	_____	_____

TIDieR checklist

Figure 22: Example of Template for Intervention Description & Replication Checklist (TIDieR).

The Consolidated Standards of Reporting Trials (CONSORT) 2010 statement suggests in item 5:

‘Authors should report on the interventions for each group with sufficient detail to allow for replication including how and when they were administered’.

(Hoffman, 2014, p.3)

Guidance is intended to apply across all evaluative study designs. While many journals endorse the CONSORT statement, reporting is still deficient. The problem arises from lack of awareness among authors about what comprises a good description and from a lack of attention by peer reviewers and editors (Schroter 2012).

Similarly, Tian (2023) states that future research investigating the effectiveness of reflexology for example, should use appropriate reporting guidelines (TIDieR) and to facilitate standardised reporting of intervention parameters (Hoffman 2014). Such strategies could have an immediate impact on methodological quality of the evidence base for reflexology. The development of research methodologies which allow a focus on both the whole system and components of the system in context is essential to take us towards a broader understanding of what is possible for the therapy of reflexology Whatley (2022).

2.7 Ethical considerations

Systematic reviews have a powerful role in influencing policy, practice, furthering research and public perception. According to Harsh (2020) the guiding ethical principles for quality research synthesis are: 1) informed subjectivity and reflexivity 2) purposefully informed selective inclusivity and 3) audience-appropriate transparency. Given that reviewers do not typically have direct access to participants of primary research, but draw on public records, it is imperative that critical reflection takes place including; consideration of the authors methodological and pedagogical orientations, assumptions they are making and how they might influence the findings of the original studies. Assessing the epistemological positioning of the authors identified in the preliminary research (Harsh 2020). Deontological ethics will be visible by the focus on minimizing threats to internal validity, external validity, internal reliability and external reliability of review findings. Indeed, one of the biggest responsibilities of the reviewer is to be alert to the common forms of biases including search biases; database bias, citation bias, availability bias, language bias, country bias, familiarity bias and multiple publications bias. The inclusion of diverse viewpoints cannot be over-stated for systematic reviewers, hence the inclusion of grey literature. Thus, critiquing the integrity of relevant studies will be informed by subjectivity and reflexivity in practice

In conclusion, this systematic review has drawn upon positivism, constructivism/interpretivism and the pluralistic strength of pragmatism to evaluate the extent to which findings are grounded in the reported evidence.

Chapter 3 Findings

3.1 Introduction

This chapter provides a narrative of the findings. A total of 48 studies were included in this systematic review. A summary of combined results of all randomized controlled trials in a 'table of characteristics' can be viewed along with this narrative. A separate table displays information on 'adverse effects & safety' of massage & reflexology. Expanded version of individual extraction forms can be viewed in the appendix.

To provide a background of the research in this field to date, a summary of previous systematic reviews and an integrative review is provided (Tian 2023). All five studies were concerned with breast cancer populations, reflecting the fact that breast cancer is the *most* studied type of cancer, albeit two included a mix (Kutner 2008; Jane 2011). Justification for four studies included in the review is given due to date of research. A PRISMA flow chart details the process and can be viewed alongside the results of this systematic review. Results of included research papers are broken down under separate headings.

3.2 Previous Reviews

Tian (2023) writes that the body of literature on effectiveness of reflexology in cancer patients is mounting with several integrative (Gholamzadeh 2019) systematic reviews (Yeun 2021; Wanchai 2020;) & meta-analysis conducted to date. These reviews focus predominantly on the management of physical symptoms and side-effects of treatment or are limited to only one type of cancer (breast cancer). More recently, researchers have begun to examine the evidence of effectiveness of reflexology on mental health outcomes in patients living with cancer, with a research question similar to the one presented in this systematic review.

To summarize Tians' (2023) review, the studies published between 2000 and 2021 were conducted across six countries including USA, Turkey, UK, Chine, Greece & Iran. Of the 15 included studies, sample sizes ranged from 12 – 286 participants

(Wyatt 2012). All studies targeted an adult population including both men and women. The types and stages of cancer were varied leading to reports of diverse cancer treatment/management modalities and phases. Reflexology delivery was delivered similarly across the included studies with several specifying the use of the original Ingham method (Wyatt 2017), manual reflexology method by Wugster (Jahani 2018) or the Bayley method (Mantoudi 2020). The delivery of reflexology involved researchers/authors of the studies (Kurt 2018) independent certified/trained reflexologists/therapists (Sharp 2010) or friends/family members trained by a reflexologist (Wyatt 2017). Reflexology interventions mostly lasted 30mins per session, generally once a week (Wyatt 2012) for a duration of two (Turkeu 2021) to eight weeks (Dickmen 2019). The intervention delivery settings included hospital wards (Stephenson 2000; Stephenson 2007) participants' homes (Wyatt 2012; Wyatt 2017; Dickmen 2019), clinics (Sharp 2010) and nursing homes (Hodgson 2012). Adherence rates ranged between 75% and 92% (Wyatt 2012; Sharp 2010). Most studies collected data from self-reported questionnaires while follow up data had intervals ranging from two (Turkeu 2021) to 10 weeks (Sharp 2010). Finally, all RCTs adopted a parallel design except for two (Stephenson 2000; Hodgson 2012) that used a cross-over design. The conclusion of the systematic review & meta-analysis was:

'There is mixed and conflicting evidence of the effectiveness of reflexology on mental health outcomes in adults living with cancer...as a result, an unequivocal recommendation cannot be made due to concerns regarding the evidence base...the use of well-established reporting guidelines, investment in well designed, high quality clinical research represent important steps to building this evidence base'.

(Tian 2023 p.29).

Justification for studies (prior to 2012)

Kutners (2008) multi-site RCT is a good example of an acceptable sample sized-study. It has strong internal validity, contains strong discussion points and captures the essential challenge of undertaking RCTs in massage and reflexology, which is the inability to clarify which aspect of care is causing positive impact - massage, touch, or good hospice care (Kutners 2008). Indeed, practices based on touch makes it difficult

to determine whether the therapeutic effect is linked to the specifics of the practice *or* to the attention through human touch and massage-like manipulation (Sikorski 2009).

Kutners (2008) study highlights the unmeasured systematic differences which would affect study outcomes and operate as confounders. For example, without a usual care control arm, the differential beneficial effect is not conclusive. Listings (2010) states that future research should try to answer the question whether it is the chemical manipulations or the therapeutic influence that results in improved mood. This approach shows a commitment to expanding the evidence base through new measurement methods and highlights the need to understand modes of action, essentially *how* massage and reflexology impacts the mind and body.

Sharps (2010) comparative RCT conducted in the UK participant size was more satisfactory than some others with 183 participants. This study is included because it sets the scene for studying *contextual effects* in therapeutic work, and the need to evaluate the relative contributions of extra physical contact and social contact in future (Sharp 2010). Such a focus is essential to moving the evidence-base forward. Fernandez-Lao (2012) randomized cross-over design deals with a new interest of the emerging population of cancer survivors. Despite small sample size (20 participants) the recommendations made are interesting to further research, including the need to investigate the *cumulative* effect of treatments encompassing patient attitudes (psycho-social) as well as immune effects of myo-fascial release.

3.3 Results

The results for this dissertation yielded 2,237 articles identified by electronic databases and registers. A total of 284 articles were screened for title and abstract relevance with a total of 188 articles excluded after inclusion and exclusion criteria were applied. In the main, articles were excluded because of one or more of the following reasons; a) study was outside of the inclusion criteria (10 year period); b) wrong study design/non RCT; c) a duplicate randomized controlled study; d) outcomes irrelevant to the review question or; e) interventions or population did not fit the inclusion criteria; f) already excluded study. A remaining 96 articles were assessed, 48 of which were further excluded for a variety of reasons that can be seen in the

screening part of the PRISMA flow chart. Articles which focused on therapeutics other than those dealing with the human touch element of massage and reflexology were excluded. Hence, the high exclusion rate. The remaining 48 articles were included in the final review.

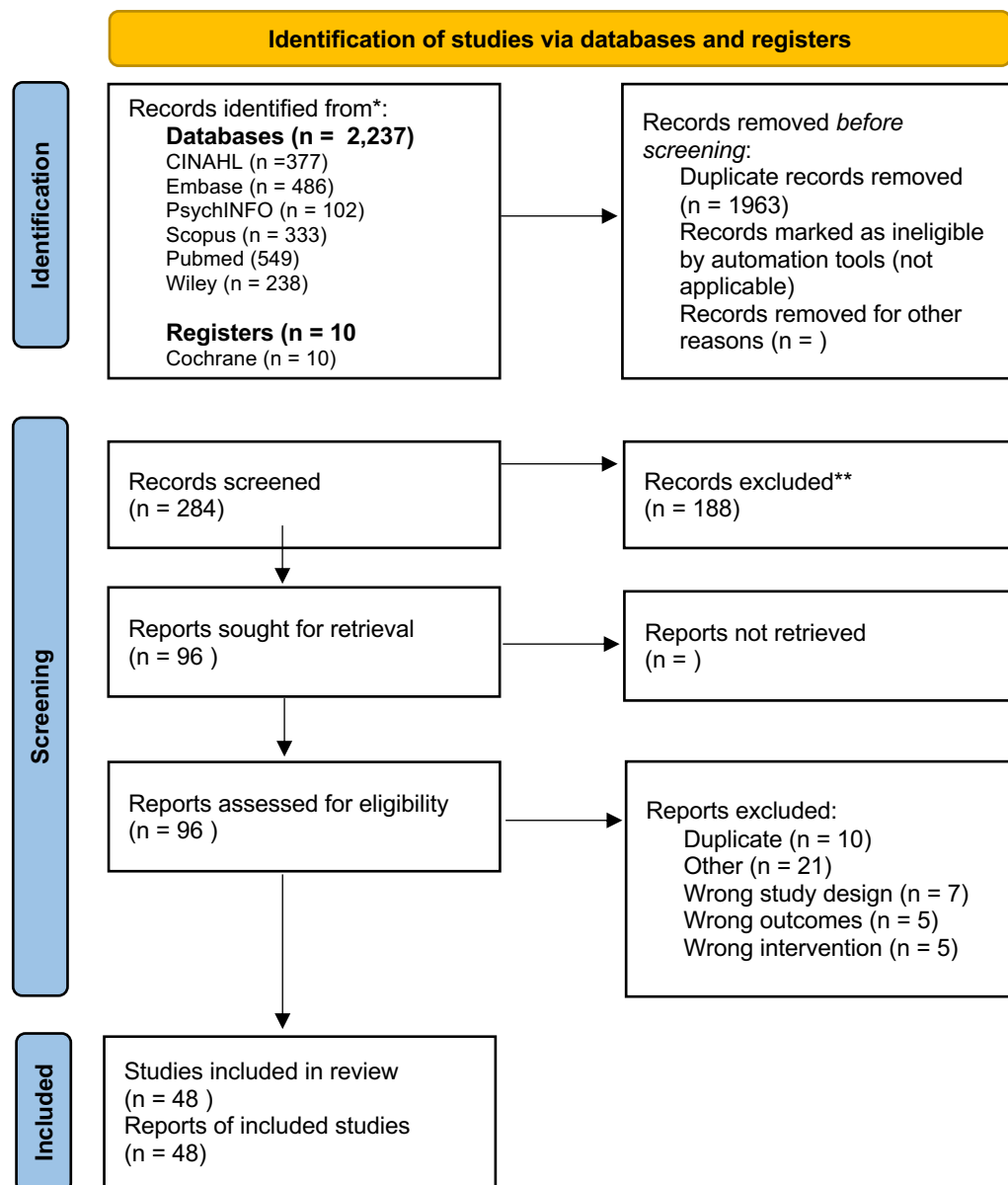


Figure 23: PRISMA Flow diagram for systematic reviews (Page 2021).

3.4 Characteristics of Included Studies & Adverse Effects

Figure 24: Characteristics of included studies tables 1 - 5

Author	<i>Milidinia et al</i>	<i>Gentile et al</i>	<i>Murat-Ringot et al</i>	<i>Toygar et al</i>	<i>Marcolin et al</i>	<i>Noh & Park</i>	<i>Donoyama et al</i>	<i>Wilkie et al</i>	<i>Uysal et al</i>	<i>Toth et al</i>
Date	2022	2020	2021	2020	2023	2019	2018	2017	2016	2013
Country	Iran	USA	France	Turkey	France	S.Korea	Japan	USA	Turkey	USA
Setting/ Treatment	National Cancer Centre Massage	Community Cancer Institute Massage	Hospital Reflex	Oncology Unit - Hospital Reflex	University Hospital Reflex & Massage	Gynecology ward – Comprehensive Hospital Aroma-self foot reflexology	Unclear – potentially Hospital AMT Japanese Massage	Own homes Massage (4 types)	Oncology Research Hospital Massage & reflex	Medical Centre Oncology Clinic Massage
Research aims	Evaluating Response to massage doses: Pain/fatigue/sleep	Anxiety	CINV/ HQoL/ Anxiety	Sleep Anxiety	Assess impact on Anxiety Pain Sleep distress	Regimen Cox's interaction Model (IMCHB)	To examine the physical & psychological effects of AMT HQoL improve ment	Effects on: Pain HQoL Analgesic doses	Determine 'effects on symptoms'	Feasibility & effects; Pain Anxiety Alertness
RCT type	7 – arm RCT	Retrospective Observe	Open label RCT	Double-B placebo control	Two-arm trial	RCT	Open-label, two-arm, parallel RCT	RCCT	Prospective RCT	3-arm pilot RCT
Participants	Adults - cancer	Adults - cancer	Digest Lung cancer	Care-givers	In-patients-cancer	Gynaecology patients with CIPN	Gynaecology patients	Adults-cancer	Colorectal cancer	Metastatic cancer -mixed
Sample size	273	749	80	66	30	63	40	29	60	39
Measurement tools	Numeric rating	Global Anxiety Measure	EORTC QLQ-C30 HADS VAS/BIQ	RCSQ Visual Analog Scale ID form	ESAS Richmond Distress thermo	Measured: Peripheral Neuropathy Anxiety depression	EORTC-QLQ-C30 HADS POMS MAC	PAT SNVR Grahams QoL	EORTC -QLQ-30 CR29 CTAE	Questionnaire VAS Pulse & respiratory rate/BPI
Duration of treatment	15, 30 or 60mins	45 mins	30mins	30mins	15-20mins	30mins	40mins	30-50mins	20mins	15-45mins
Length of study	4 wks	4yrs: 2015-2019	4 wks	3 wks		6 wks	8wks	4wks	5 wks	3 'visits'
Follow-up	4 wks				6mths	6 mths	8 wks			1wk & 1mth
Practitioner		600-900hrs	3Q reflex					5 licensed	Researcher	'Prof'/3yrs
Outcomes/ adverse effects	Cluster-intensity decreased 60min massages	Massage decreased anxiety	Better manag nausea, anxiety	Improved sleep quality	Improved sleep in reflexology	Reduction of anxiety/ depression	Less anger/hostility Insomnia in AMT group – reduced complaint severity	Pain & resp rate reduced	Reduced pain, QoL	Modest sleep Improve Trends – improved anxiety

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Author	<i>Kutner et al</i>	<i>Zengin & Aylaz</i>	<i>Mazloum et al et al</i>	<i>Anderson et al</i>	<i>Ozdelikara & Tan</i>	<i>Turkeu et al</i>	<i>Dickmen et al</i>	<i>Wyatt et al</i>	<i>Serfaty et al</i>	<i>Sikorskii et al</i>
Date	2008	2019	2023	2022	2017	2021	2019	2012	2012	2021
Country	USA	Turkey	Iran	USA	Turkey	Turkey	Turkey	USA	UK	USA
Setting/ Treatment	Hospice Massage	Oncology Hospital Reflex/Sleep Hygiene(SH)	University Reflex	? Reflex	Chemo Unit Reflex	University Reflex	Home Reflex	13 medical Oncology Clinics Reflex	Oncology Hospital A-massage/ CBT	Home Reflex
Aims	Pain Distress HQoL	Examine effects on sleep quality, fatigue	Compare effects of foot bath & reflex on cancer- related fatigue (CRF)	Evaluate effects of reflex on pain & nausea	Effect on QoL	Examine effects on anxiety Depression QoL(Watsons theory of caring)	Effect of pain Fatigue QoL	Evaluate safety & efficacy of reflexology versus LMP	Effects on anxiety depression & examine trends	Examine symptoms responses
RCT type	RCT clinical trial	Pre-test semi- exp (randomized)	RCT	Pilot RCT Convenience sampling	'Study' Control & exper groups	Single-blind RCT- pre- test/post- test/control	Single-blind RCT	Longitudinal RCT Comparative	Single-blind RCT Parallel group	RCT
Participants	Advanced cancer	Chemo patients	Radiotherapy patients	Cancer patients	Breast cancer	Gynecolog ical cancer patients	Gynecolog ic cancer patients	Adv breast cancer	Adults- Cancer (all stages)	Adv breast cancer
Sample size	380	167	62	40	60	62	80	385	39	256
Measure Tools	MPAC NPS BPI McGill	PSQI FSS	Multi- dimensional (MFI) Fatigue Invent	VASWang- baker FACES pain rating scale/survey	ID Forms EORTC- QLQC -30	Beck Anxiety & Dep Inventory EORTC QLLQ- C30	BPF Multi- dimensional QoL scale	Physical Function Subscale FACTT-B BFI/Brief PI	HADS POMS-TMS Psychlops EUROQoL	Bayliss tool MDASI Weekly assess
Duration	30mins	20mins30mins	20mins	20/25mins	30-40mins	30-45mins	60mins	30 mins	60mins	30mins
Length of study	2 wks	8wks	2wks			2wks	8wks		3mths	4wks
Follow-up	3 wks		1wk, 2wks, 4wks	Single reflexology		2days, 1 week	3,8,12wks evaluation	Wks 5&11 - interviews	3 & 6 mths	Weekly calls
Practitioner		Researcher (5wks train)	Researcher (3 hrs training)	PI: 50 practice hrs	Researcher			Reflexologist (22yrs exp)	Dip trained	Care-givers trained-
Outcomes/ adverse effects	Massage mood & QoL imp	Reduced fatigue,sleep quality better	Both reduced fatigue. Reflex more effective	Decreased pain; nausea	Sig improve- in symptoms	Reduced anxiety QoL better	Less fatigue after reflexology	Reduced dyspnea; Reflex safe.	Improve with <i>both</i> interventions	Reflexology useful for pain manage..

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Author	<i>Kinkead et al</i>	<i>Miladina et al</i>		<i>Lopez et al</i>	<i>Tarrasch et al</i>	<i>Mantoudi et al</i>	<i>Sharp et al</i>	<i>Kurt & Can</i>	<i>Jahani et al</i>	<i>Tabatabaee et al</i>
Date	2018	2021		2022	2018	2020	2010	2018	2018	2016
Country	USA	Iran		USA	UK	Greece	UK	Turkey	Iran	Iran
Setting/ Treatment	University Swedish Massage	Oncology Hospital Massage		Academic centre Massage	Cancer Centre Reflex	Outpatient palliative Reflex	Oncology Centre Reflex	Chemo Unit Reflex	Hospital (two) Reflex	Oncology Hospital Therapeutic Touch (TT)
Aims	Effect of massage on cancer- fatigue (CRF)	Comparison: Massage, music, Standard care		Feasibility & efficacy of 2 types of massages on peripheral neuropathy (CIPN)	Evaluate effects of reflex on QoL, sleep disturbance & fatigue in B cancer	Compare effects of reflexology & relaxation on pain, anxiety, depression	Evaluate effects of reflexology on QoL in women	Evaluate Effective Ness of reflex on CIPN	Effect of reflex on pain intensity & anxiety	Evaluate effect Of TT on pain parameters – patients with cancer
RCT type	3-arm RCT Clinical trial	3 parallel group trial RCT		Pilot RCT: Single-blind	Exp/control study	Comparative RCT	Comparative RCT	RCT	Clinical trial	3-arm RCT
Participants	Breast cancer	Cancer patients		Breast & Gastro	Breast cancer	Cancer patients	Breast cancer	Breast & Gastro	Metast cancer	Cancer patients (male)
Sample size	66	114		71	50	80	183	60	84	90
Measure tools	Q-LES-Q40 MFI PROMIS	Self-report Pain & numeric rating scale		Pain quality Assessment (PQAS) Expectation	LFS GSDS MQOLSEA NRS (Pain)	GBPI HADS Health Survey	TOI FACT-B HADS MRS	Patient ID Form EORTC-CIPN 20 BPI	Spielberg Question.. VAS Question...	BPI Demographic Questionnaire
Duration of treatment	45mins	15mins		30mins		30mins	60mins	20mins	30mins	15mins
Length of study	6wks	4wks		4 OR 6wks	10wks		8wks	6wks	3 days	4wks
Follow-up		2wks		10wk	4wks					
Practitioner	Licensed therapist			3 therapists 15yrs exp	Senior reflexologist	Researcher		Certified reflexologist		TT practitioner (15yrs experience)
Outcomes/ adverse effects	Reduced fatigue	Decrease in pain intensity & fatigue		Demonstrated <i>dose intensity</i> is important	Amelioration of CRF in reflexology	Significant improvement in anxiety	Massage was better than massage	Reflex - quality of life & CIPN	Reflex effective to mitigate intensity...	TT – Safe method

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Author	<i>Izgu N et al</i>	<i>Fernandez Lao et al</i>	<i>Listing et al</i>	<i>Simsek et al</i>	<i>Jane et al</i>	<i>Taylor et al</i>	<i>Kuon et al</i>	<i>Vergo et al</i>	<i>Cutshall et al</i>	<i>Ovayolu et al</i>
Date	2019	2011	2010	2022	2011	2014	2019	2018	2017	2014
Country	Turkey	Spain	Germany	Turkey	Taiwan	USA	USA	USA	UK	Turkey
Setting/ Treatment	Chemo Outpatients Massage (CM)	Oncology Unit Myofascial Release	University Hospital Classic Massage	Research Hospital Reflex	Oncology Unit Massage (MT)	In-patient setting & Home Massage	Medical Centre Massage	Academic Med Centre Massage	Chemo Unit Hand Massage	Oncology Dept Aroma & Massage
Aims	Investigate effect of CM on CIPN & QoL	Investigate effect of MR/ Assessed influence of <i>attitude....</i>	Investigate the efficacy of stress perception & mood disturbance	Evaluate effect of reflex on nausea, vomiting & anxiety	Comparison of MT & social attention (SA) on pain, mood, relax/ sleep	Assess of immediate & cumulative effect of massage in AML	Evaluate a pilot massage programme: Symptom management	Examine immediate symptom relief from reiki or massage	Assess feasibility of hand massage in outpatient chemo unit	Assess effectiveness of both forms; Administered in various ways
RCT type	Pros RCT	CrossOver RCT	RCT	RCT	RCT	Mixed-M RCT	Single-arm Feasibility	Retrospective Analysis	Quasi-pilot experimental	3-arm RCT
Participants	Breast cancer	Cancer (survivors)	Breast cancer	Breast cancer	Bone metastasis	Acute myelogenous leukemia	Haematologic malignancies	Hospitalized patients – (cancer/non)	Chemo patients	Breast cancer
Samplesize	40	20	34	58	72	43	109	1585	40	280
Measure ment tools	S-LANSS EORTCQLQ- CIPN20 Nerve conduction studies	Holter electro- recordings Mood states Attitude to massage	PSQ BSF Endocrine measures Blood samples	Patient Info Rhodes Index of nausea (RINVR) STAI1-11	PPI-VAS Mood, relaxation, sleep (VAS) DP MP	Self-report EORTC- QLQC30) STAI Form McGill Pain (SF-MPQ)	Post surveys	1.1 Likert Scale	Visual Analog Scale (VAS)	Questionnaire QoL scale Rotterdam Symptom Checklist
Duration of treatment	30mins	40mins	30mins	40mins	45mins	50mins	20-30mins	15-30mins	20mins	35mins
Length of study	12wks	2wks	5wks	6wks	3wks	7wks	11.5months			4wks
Follow-up	4wks		6wks							
Practitioner	Qualified	Therapist5yrs ex		Research	Author train	Certified	10yrs exp		Volunteers	
Outcomes/ adverse effects	CM prevents CIPN & improves QoL	Massage elicited emotional congruence	Less anger & mood disturbance	Sig reduction of anxiety in reflex group	Pain reduct statistically & clinically meaningful	Significant improvement in stress & HQoL	Improved relax anxiety& management	Immediate symptom relief after 1 st session	Massage – 'authentic caring connection'	Aroma massage – especially effective

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Author	Rambod et al	Fernandez-Lao et al	Grant et al	Nourmohammandi et al	Wyatt et al	Gholamzadeh	Abdelaziz & Mohammed	Frambes et al	Wyatt et al
Date	2019	2012	2022	2018	2017	2023	2014	2017	2022
Country	Iran	Spain	Australia	Iran	USA	Iran	Egypt	USA	USA
Setting/ Treatment	Haematology /Oncol wards Reflexology	Phys Therapy Uni Clinic (lab) Myofascial-release	Cancer Hospital Reflex/ Acu puncture	? Reflex	Home-based Reflex vs Attention control	Hospital Reflexology vs usual care	Surgical ward Cairo Uni Foot Massage (FM)	Oncology clinics Reflex	Homes of care-givers Reflex vs meditative practice
Aims	Evaluate effect of reflex: Fatigue/pain/ Sleep quality	Evaluate influence of patients attitudes; massage on pressure sensitivity	Observe the effects reflexology and or acup on multiple self-report	Aim to cultivate the effect of reflex on fatigue severity-cancer	Determine effects of home-based reflex by care-giver; effects	Effect of reflex on QoL among patients with CIPN receiving chemo	Evaluate effects of FM on post-operative pain & vital signs	Explore whether intervention effects are moderated by care-giver characteristics	Investigate the optimal sequence of evidence-based comp therapies; fatigue, dep,
RCT type	RCT; pre-post design	Randomized Single-blind cross-over	Observational	D-blind pre-post Clinical T	RCT	RCT	Quasi-experimental design	RCT	SMART
Participants	Lymphoma patients	Breast cancer survivors (BCS)	Chemo patients	Breast Cancer patients	Adv breast Cancer patients	Colorectal patients	Breast cancer	Care-givers of cancer patients	Cancer patients & care-givers
Samplesize	72	20	330	57	256	40	60	256	471
Measure ment tools	MFI Numerical scale PSQI	Saliva samples PPT ATOM scale	ESAS	FFS	MDASI PROMIS QLI/MSPSS Quality of R	EORTC QLQ-C30 EORTC QLQ-CIPN20	Structured Questionn VAS Vital signs	PROMIS	BFI MDASI PROMIS
Duration of treatment	30mins	40mins	20mins	20mins	30mins	20mins	20mins	30mins	30mins
Length of study	8wks (no more)	2 sessions	3yrs	4wks	4wks	4wks		4wks	12 wks
Follow-up	'short'			8wks	7wks				
Practitioner	Reflexologist		5yrs exp		Reflex train	Researcher	Surgical Nurs	Care-givers	Reflexologist
Outcomes/ adverse effects	Reflex reduced fatigue, pain, improved sleep quality	Parasympath & immune effect of intervention – modulated by attitude...	Clinically & significantly sig change in all symptoms	Reflex decreased fatigue severity in cancer pa	Reflex is efficacious in reducing cancer symptoms	Reflex relieved neurotoxicity	Supports effectiveness of FM as a modality to relieve pain	Fatigue levels lower in are-givers providing reflex	No differences between intervention effects

Summary of Adverse effects

Figure 25: Summary of Adverse Effects.

Author	Adverse effects	Author	Adverse effects
1. Miladinia et al (2021)	None reported	25. Mantoudi et al (2020)	None reported.
2. Gentile et al (2020)	None reported	26. Sharp et al (2010)	None reported. <i>'Reflexology can be considered an evidence-based complementary intervention for improving QoL of women with breast cancer'.</i>
3. Murat Ringot et al (2021)	None reported. <i>'None of the adverse effects experienced by 12 participants were attributed to reflexology' (Dr assess)</i>	27. Kurt & Can et al (2018)	None reported. <i>'Reflexology increased the level of quality of life functions related to CIPN in a positive way'.</i>
4. Toygar et al (2020)	None reported.	28. Jahani et al (2018)	None reported. <i>'Notable point is that none of these other studies (cited) have reported unfavourable side-effects for reflexology'.</i>
5. Marcolin et al (2023)	None reported. <i>'Reflexology did not lead to increased intensity of discomfort'</i>	29. Tabatabaee et al (2016)	None reported.
6. Noh & Park (2019)	None reported. <i>'No harm associated with study intervention'.</i>	30. Izgu et al (2019)	None reported. <i>'No severe effects have been reported'.</i>
7. Donoyama et al (2018)	None reported.	31. Fernandez et al (2012)	None reported.
8. Wilkie et al (2017)	None reported.	32. Listing et al (2010)	None reported.
9. Uysal et al (2016)	None reported.	33. Simsek et al (2021)	None reported.
10. Toth et al (2013)	None reported.	34. Jane et al (2011)	None reported.
11. Kutner et al (2008)	None reported. <i>Standard adverse forms completed if reported'.</i>	35. Taylor et al (2014)	None reported.
12. Zengin et al (2019)	None reported.	36. Kuon et al (2019)	None reported. <i>'It would be interesting to capture more markers of disease severity and assess any correlation to self-reported effect in future studies'.</i>
13. Mazloun et al (2023)	None reported.	37. Vergo et al (2018)	None reported.
14. Anderson et al (2022)	None reported.	38. Cutshall et al (2017)	None reported.

15. Ozdelikara & Tom (2017)	None reported <i>'Reflexology can be safely used by patients with cancer who are undergoing chemo'.</i>	39. Owayolu et al (2014)	None reported.
16. Turkeu et al (2021)	None reported. <i>'Patients in current study did not experience any side-effects – it should be kept in mind in future research that there may be side-effects'.</i>	40. Rambod et al (2019)	None reported. <i>'Patients were provided cell phone number of the researcher in case of side-effects or complications'. Future studies recommended to assess effects of intervention.</i>
17. Dickmen et al (2019)	None reported.	41. Fernandez-Lao et al (2011)	None reported.
18. Wyatt et al (2012)	None reported. <i>'The current study was the first to have a data & safety monitoring committee which quarterly reviewed the data for adverse effects & incorporated a mechanism for reporting adverse events'.</i>	42. Grant et al (2022)	None reported. <i>'This cohort study provides a real-world example of complex QoL symptoms & how reflexology & acupuncture can mitigate symptoms'.</i>
19. Serfaty et al (2012)	None reported.	43. Nourmohammandi et al (2018)	None reported. <i>'Reflexology appears to cause physiological changes that increase comfort in patients' (Jin & Kim 2005).</i>
20. Sikorski et al (2021)	None reported.	44. Wyatt et al (2017)	None reported.
21. Kinked et al (2018)	None reported. <i>'Observed enhanced quality of life'.</i>	45. Gholamzadeh et al (2023)	None reported. <i>'The effects of reflexology should be evaluated over longer time periods ie 6-12 weeks'.</i>
22. Miladinia et al (2021)	None reported.	46. Abdelaziz & Mohammed (2014)	None reported. <i>'Using techniques such as reflexology is a very valuable adjunct to normal nursing care; safe, inexpensive, non-toxic, evidence-based'.</i>
23. Lopez et al (2022)	None reported.	47. Frambes et al (2017)	None reported.
24. Tarrasch et al (2018)	None reported.	48. Wyatt et al (2022)	None reported.

3.5 Reflexology

Twenty four studies (50%) of the total 48 studies included in the review are based on reflexology; one of which included reflexology & sleep hygiene (Zengin 2019); one reflexology & footbath (Mazloun 2023); one reflexology versus attention control (AT) (Wyatt 2017) and one reflexology versus acupuncture (Grant 2022). Only two (4.1%) compared reflexology to massage (Uysal 2016; Marcolin 2023).

3.6 Massage therapy

Sixteen studies (33%) of total included studies in the review researched massage. This includes AMT Japanese massage (Donoyama 2018) and hand massage (Cutshall 2017) and massage compared to social attention (SA) (Jane 2011).

3.7 'Other' intervention of included studies

The remaining six studies constitute 12.5% of the total included. These are variations including one study of reflexology and aromatherapy (Noh & Park 2019); one study on massage and aromatherapy (Ovayolu 2014); one on aromatherapy and cognitive behavioural therapy (CBT) one on therapeutic touch (TT) (Tabatabee 2016); two on myofascial-release (MO) (Fernandez-Lao 2012; Fernandez-Lao 2011). All of these were meaningful studies, and can be justified for inclusion.

3.8 Dates of included studies

In the past decade there has been an incremental upward trend in the amount of research undertaken. A peak time of activity in reflexology and massage research appears to be in 2018, where six RCTs, two clinical trials and one retrospective analysis were carried out, spanning USA, Turkey, Iran, UK and Japan. Since 2018, there has been a steady and consistent amount of research carried out which demonstrates the increasing interest in this subject area. Currently, the greatest amount of research is being undertaken in USA, Turkey and Iran with USA leading in terms of volume of studies.

3.9 Countries of included studies

Out of the 48 studies, 31% of these were based in the USA, a total of 15 studies; followed by Turkey with 20% of the research totalling 10 studies; 16% of the total included studies were based in Iran, a total of 8 included studies. A total of (6%) of the included studies were UK based. France and Spain account for only two included studies. The following countries collectively represent 14% of the total literature on reflexology and massage: Germany, Greece, Egypt, Japan, Taiwan, South Korea and Australia.

3.9.1 Population of included studies

In accordance with the aims of the review, the included population in the studies are cancer patients. There are however, variations in how this population is described in the literature. For example, 15 (31%) of the total are 'cancer patients' or patients receiving chemotherapy/radiotherapy' or 'adults with cancer'. Another 13 studies were exclusively breast cancer patients (27%). Four studies focused on gynaecology cancer patients (8%); while colorectal, metastatic and breast & gastrointestinal patients collectively amounts to six studies (12.5%); there is one study for each of the following cancer types; digestive & lung cancer, bone metastasis, acute myelogenous leukemia, haematologic malignancy and lymphoma patients accounting for 10% of the total studies. Finally, two studies (4%) focused on cancer survivors and three studies (6%) on care-givers. Carers are not the focus of the research, there is however an upward trend in the literature on reflexology and massage which incorporates this population group. This is because cancer patients and cancer survivors are inextricably linked to care-givers. However, it is highly debatable whether informal care-givers performing interventions is suitable against a current background of scepticism and a clear need for quality assurance in studies.

3.9.2 Sample sizes

Sample sizes in the RCTs ranged from 29 cancer participants (Wilkie 2017) to 280 breast cancer participants in a 3-arm RCT (Ovayolu 2014). The lowest participant size was 20 cancer survivors in both a cross-over RCT (Fernandez-Lao 2012) and a single-

blind cross-over on breast cancer survivors (Fernandez-Lao 2011) both undertaken in Spain. On the other hand, the highest participant number within the RCTs are 385 advanced breast cancer patients, a longitudinal comparative RCT (Wyatt 2012) and 471 cancer patients and their care-givers; a sequential multiple assignment randomized trial (SMART) (Wyatt 2022). The vast majority of included studies exhibited the region of 30 participants to 90 participants.

At the higher end of the scale, and within the non-RCTs, participant numbers ranged from 330 in an observational study (Grant 2022); 749 (Gentile 2020) in retrospective observational study and 1585 (Vergo 2018) a retrospective analysis. Most authors acknowledge the need for larger studies in future.

3.9.3 Types of studies included

A total of 28 out of 48 studies (58.3%) were a combination of either single, double blind, two or three arm RCTs with the exception of one seven arm RCT (Milidinia 2021); The remaining 41% includes a variety of variations: three studies featured as 'study with control & experimental group' or 'pre-test semi-experimental' (Zengin 2019; Tarrasch 2018; Ozdelikara 2017); two were named 'clinical trials' (Jahani 2018; Kinkead 2018); two were comparative (Mantoudi 2020; Sharp 2010); two 'quasi-experimental' (Cutshall 2017; Abdelaziz & Mohammed 2014); two cross-overs (Fernandez-Lao 2012; Fernandez-lao 2011); one mixed methods RCT (Taylor 2014); one pilot-convenience sampling RCT (Anderson 2022); one observational (Grant 2022); one retrospective observational (Gentile 2020); one longitudinal & comparative RCT (Wyatt 2012).

3.9.4 Settings of included studies

The majority of studies, a total of 31 studies (64.5%) were carried out in a hospital setting of some description. A further seven studies (14.5%) were based in an academic setting such as a university, academic or medical centre. Six studies (12.5%) were carried out in participants home including one which was a combination of 'home & in-patients'. One study setting specifically stated a hospice, while three studies (6.25%) were unclear about the setting in which the study was carried out.

3.9.5 Blinding of included studies

Ideally, the participants, those administering the intervention and those assessing outcomes and analysing data should all be blinded. Otherwise, prior knowledge may consciously or unconsciously influence the behaviour of any of these people. Of the 48 studies, a total of 22 studies (45.8%) did not provide details of blinding. A further three (6.25%) did not require blinding because they were not RCTs (Grant 2022; Gentile 2020; Vergo 2018). The remaining 23 studies (47.9%) did reference some form of blinding, with attempts to mask the researchers and individuals involved in the data collection process. Most studies wrestle with the issue of blinding, and a common theme has emerged in the literature:

‘Owing to the nature of the randomized conditions, participants were not blinded to the group assignment’

(Sikorskii, 2020, p.4)

‘Because of the nature of the investigation, participants, massage therapists and coordinators were unmasked’.

(Miladinia, 2022, p.3)

These comments by authors form part of a bigger discussion about the utility of randomized controlled studies in massage and reflexology research, and will be addressed in the next chapter.

3.9.6 Randomization of included studies

There is significant heterogeneity when it comes to the randomization process in the included studies. Murat-Ringot (2021) study used randomization by type of cancer. On the other hand, Simsek (2021) used block randomization according to age and drug doze. Mantoudi (2020) used stratified random sampling using an experimental design. The study by Mazloun (2023) randomly allocated participants to footbath or reflexology through drawing random sequences (randomization website). Taylor

(2014) accomplished randomization using a computer-generated assignment list and masked using envelopes. Milidinia (2021) says that random allocation was only known by the research assistant who had no involvement in the rest of the trial. Similarly, Izgu (2019) study used a random number table generated by software, operated by the second researcher who was not involved in the intervention procedures. Jane (2011) Wyatt (2017) Sikorskii (2021) and Wyatt (2022) minimized potential confounders using a computerized minimization programme. Fernandez -Lao (2012) study randomly assigned participants to either experimental or placebo using a coin flip. Whereas Nourmohammandi (2018) used randomization based on the days of the week. Dickmen (2019) says patients were ‘randomly assigned via a random number table to one of four groups by the researcher.’ Ozdelikara & Tam (2017) states that a ‘random sampling method’ was used. Finally, Anderson (2022) Rambod (2019) and Cutshall (2017) used convenience sampling.

One study expressed notable confounding and bias because of the imbalanced numbers:

‘To gain more experience with the massage the authors randomized twice as many patients to the massage intervention as to the no-touch control intervention or the usual care groups’.

(Toth, 2013, p.651)

Moving the research forward, Wilkie (2017) suggests that random assignment to groups using stratification by *gender* and on *baseline pain intensity levels, QoL scores* are an important methodological change that is needed to improve the design of future studies.

3.9.7 Adverse Effects & Safety

There is a dearth of information relating to adverse outcomes within the literature. While Kutners (2008) states that the research dispels the common concern about adverse events or mortality among the advanced cancer population. Furthermore, Listings (2010) cites the point that there is no evidence for the spreading of tumour cells by massage therapy (Corbin 2005). As can be seen on Figure 25 table of adverse

effects, none of the included 48 studies included in this review report *any* adverse effects from reflexology or massage. On the contrary, there are numerous comments by authors which point to the *safety* of these therapeutic modalities. For example:

‘A notable point is that none of these other studies (cited) have reported unfavourable side-effects for reflexology’.

(Jahani, 2018 p.402)

Turkeu (2021) cautions that despite a lack of evidence of any adverse effects, future researchers should bear in mind that there *may* be side-effects. Significantly, Wyatts (2012) study was the first to employ a data & safety monitoring committee for adverse effects incorporating a reporting mechanism. This highlights a promising new direction for improving research quality, led by a prominent author in the field of massage and reflexology. A recent integrative review recommends further studies with consideration to potential side-effects (Gholamzadeh 2019). Strengthening this area in the research with robust protocols on safety will elevate the evidence-base via quality reporting methods.

3.9.8 Follow-up in included studies

A major theme emerging from the literature is the need for adequate follow up. Follow-up periods in the studies were also very variable ranging from one week (Turkeu 2021) to six months in three studies (Serfaty 2012; Noh & Park 2019; Marcolin 2023); a two week follow-up (Milidinia 2021); 3 week follow up (Kutner 2008); 6 week follow-up (Listing 2010); 7 week follow up (Wyatt 2017); 10 week follow up (Lopez 2022); two studies had an 8 week follow up (Donoyama 2018). The most common follow up period was over 4 weeks which appeared in five studies (Mazloun 2023; Milidinia 2021; Izgu (2019); Terrasch (2018) and Toth (2013). A further three studies were a combination of 3, 5, 8 and 11 weeks of ‘evaluations’ or ‘interviews’ and one which consisted of weekly calls. It has been suggested that the effects of reflexology should be monitored over longer time periods and up to 12 weeks (Gholamzadeh 2023). Taking this approach would elicit the added benefit of uncovering both positive effects and any potential adverse effects in populations (Jane 2011). Adequate follow up,

length of treatment and overall study are linked to the aim of understanding the mechanisms and modes of action. This is discussed in the next chapter.

3.9.9 Practitioners in included studies

Out of the 48 studies, sixteen (33.3%) of these utilised a qualified practitioner who had some form of experience ranging from 3 years to 22 years, and others were mentioned as being 'licensed therapists' affiliated with a particular institute. Another 33% of the studies were not accounted for in respect of therapist credentials or experience. In eleven studies (22.9%) the researcher, or principal investigator (PI) appears to have undergone training of varied length in the specific technique (massage or reflexology). Three studies (6.25%) included carers as volunteers while one study involved trained surgical nurses (Abdelaziz & Mohammed 2014). This level of heterogeneity is not helpful for a number of reasons and hampers attempts to standardize interventions.

3.10 Measurement tools employed in studies

Variations of the European Organization for Research and Treatment of Cancer (EORTC-QLQ-C30) appear ten times in the included studies, accounting for 20.83% with a myriad of other tools making up the 79.17%. The EORTC-QLQ-C30 tool was developed over 25 years ago as an integrated measurement system for evaluating the quality of life of patients participating in international clinical trials. The use of the European Organization for Research and Treatment of Cancer (EORTC-QLQ-C30) is prevalent in the literature. Davda (2021) writes that the reliability analysis in terms of internal consistency for multi-item subscales yielded similar results to previous studies in different populations (Aaronson 1993; Cankurtaran 2008). Currently, it may not be possible to make generalised statements regarding the robustness of results of any of these studies, as well as their applicability in patients with all types of cancer, the studies do provide important insights into the use of the questionnaire in certain populations. Moschopoulou (2021) writes that a more contemporary approach to the study of quality of life acknowledges the multidimensional and dynamic impact of cancer involving both psycho-social *and* physical elements. Spiritual dimensions may also be relevant.

As the research approaches evolve to uncover the mechanisms of actions, so too will the measurement methods required to assess the actual impact of massage and reflexology. The over reliance on such tools could potentially lessen as a whole-systems approach is taken. Alternative methodologies are explored in the 'Discussion' chapter and form part of a much larger discussion.

Chapter 4 Discussion

4.1 Introduction

This chapter begins with a summary of potential mechanisms by which massage and reflexology may work including the utility of massage and reflexology for mental health. Important elements involved in the research process are then discussed specific to randomized controlled studies (RCTs) but also widening the scope of the research to observational and qualitative studies, reflecting a pragmatic paradigm. ‘Real life’ studies present opportunities to ask more sophisticated questions about therapies and may be more appropriate to complement the current evidence-base in massage and reflexology. Related concepts such as quality of reporting, complex interventions, efficacy & effectiveness studies, template for intervention description & replication (TIDieR), research culture, measurement tools and finding the way forward form the structure of this chapter. These all play an integral role in building and evaluating the evidence-base.

4.2 Mechanisms of action

Jing (2022) writes that regardless of the inherent mechanism of reflexology, the true effects of reflexology cannot be underestimated. Interestingly however, the determination of the usefulness of therapies requires an understanding of their biological plausibility *before* the development of appropriate research to test for safety and efficacy (Whatley 2023). Some of the potential mechanisms explored are very promising indeed.

One inquiry which relates to both massage and reflexology is the capacity of fascia and fascial manipulation to facilitate a range of effects (Liptan 2010; Findlay 2012). Positive reactions to reflexology could be instigated by changes in the structure of and mechanisms of fascia in its many guises ranging from mechanical to electrical and from musculoskeletal to molecular (Whatley 2023). It is considered feasible that therapists using sustained pressure through compression, stretching or twisting of the myofascial system can affect a change in the tissue in *other* systems. While there is

scant evidence to detect how sensory cells adjust to mechanical stimuli, recent research proposes that investigating visceral fascia that closely relates to organs that supports them, may be richly innervated by fibres from the autonomic nervous system and thereby affect metabolic behaviour (Stecco 2021). Further studies have supported this view of manual manipulations of fascia globally affecting the autonomic nervous system (Schliep 2003). Indeed, the manipulation of fascial layers during reflexology may have something to add about the alleviation of pain and improved lymph flow (Whatley 2023).

In its gentlest form, reflexology can induce relaxation and improve quality of sleep (Bakir 2018; Alinia-najjar 2020). Research indicates that there are brain alterations during a reflexology session emitting cerebral activity in brain waves usually seen in a sleep state (Esmel 2017). Relaxation and the quality of sleep has benefits for the immune system as well as in anxiety and depression (Segerstrom 2010). Furthermore, the beneficial nature of human touch is well documented (Reeve 2020). Reflexology can enhance relaxation and demonstrates an effect on anxiety and related conditions (Ellis 2013; Bidgoli 2017; Bahrami 2019). Based on such evidence it is feasible that reflexology may become a mechanism for improvement via the enhancement of relaxation alone.

Whatley (2023) says that given the range of benefits reported from improved muscle tension and pain to hormonal balance and digestive functioning, it is feasible that what happens in reflexology is akin to mechano-transduction. The theory deepens because there appears to be much more to the impact of pressure on skin, and even effects on the cells themselves (Ingber 2008). This suggests that all varieties of manual therapies including reflexology could have an effect on cellular activities. There is also evidence that haemodynamic effects (measures of cardiovascular function) can be brought about through reflexology points in the feet, making it feasible that both reflexology and osteopathy are achieving similar outcomes in discrete parts of the body (Jones 2012). The nerve impulse theory suggests that benefits of reflexology are brought about through modulation of the central nervous system and also a widely held belief that the release of endorphins may help reduce pain and increase wellbeing (Whatley 2023).

Finally, healing rituals may have profound power, and these are inherent in biomedicine as well (Kaptchuk 2002; Kaptchuk 2011).

4.3 Massage, Reflexology & Mental Health

Depression is a common comorbidity in cancer cases, affecting more than 10% of patients. Smith (2015) tells us that stress beyond the coping mechanisms of the patient may result in a major depressive disorder and that the rate of depression in cancer patients is thought to be up to three times higher than in the general population. Moreover, as evidenced in the included studies of this systematic review, there is a strong need to identify and treat depression and thereby improve quality of life in cancer patients. The impact of mood and mental wellbeing on cancer progression is considered important by doctors and patients with more than 70% of oncologists and 85% patients believing that mood affects the progression of cancer (Lemon 2004).

The impact of massage on mental health is nuanced, for example, a prominent researcher Dr Rapaport (2018) writes that although data has suggested that massage may help decrease problems with depressed mood or acute anxiety, less information is available regarding the use of massage as a therapy for depression or anxiety disorders. Current data do suggest that massage *may* have some benefit as at least an adjuvant to conventional therapies. Furthermore, some data suggests that massage may actively decrease hypo-thalamic pituitary activity, have a positive effect on immune function, enhance parasympathetic tone and modulate brain activity (Rapaport 2018). Therefore, massage therapists operating as an additional resource, supports the view of integrated oncology with the potential to help cancer patients and survivors with their symptom management.

With the growing interest in spiritual aspects of cancer care, the role of spirituality in cancer-related symptoms is becoming increasingly important. Indeed, the current assessment of spirituality (assessing peace, faith, meaning) may overlap closely with cancer-related symptoms assessed (Miller 2022). Spirituality research in cancer care is in a nascent stage.

4.4 Quality of Reporting & Randomized controlled trials (RCTs)

Designing and conducting CAM interventions is challenging, requiring a lot of planning to account for the myriad of threats to internal and external validity (Sikorskii 2009). Currently, the fundamental flaw in the CAM literature is that many systematic reviews incorporate several CAM without *distinguishing* between them and focus on only *one* kind of cancer limiting generalisability of results or are outdated (Calcagni 2019). Findings show a lack of convincing method as most of the studies fail to report adequate blinding and randomization (Buchanan 2005; Efficace 2006; Wilkinson 2008; Ernst 2009; Kim 2010; Ersnt 2011; Pan 2014; McVicar 2016). A clear interpretation of the results is difficult due to heterogeneity of methods, small sample sizes and the high risk of bias confounding the reading of the results. Indeed, performance bias was a common finding in the included studies, while studies which did not use randomization are open to selection bias.

On other hand, recent studies have flourished, albeit methodological flaws and high risk of bias is still evident (Darabpour 2016; Uysal 2016; Wyatt 2017; Ozdelikara 2017; Ayik 2018; Donoyama 2018; Massingill 2018; Kurt 2018; Miladinia 2021). Improved future trials should be multi-centric, tested interventions should be administered by different practitioners, which would be a more truthful representation of CAM (Calcagni 2019). Arguably the inherent problems are a reflection of some of the limitations of the randomized controlled method itself. As Price (2014) writes, RCTs are gold standard for assessing efficacy, but it is important to understand their limitations and where certain questions are infeasibly for RCTs to answer.

Price (2014) says that all RCTs aim to minimise potential confounders and select a pure population; such strong internal validity comes at the cost of external validity. This systematic review of the literature demonstrates this very well, because the findings of nearly all studies state the 'limited generalisability' in their limitations sections leading to repetitive rhetoric. The results of the studies are in many respects positive, but the failings of the selected methodologies are apparent in relation to the therapies being studied. This systematic review backs up the current position which is that the era of the evidence-based hierarchy is being redefined; different study designs should no longer be ranked in vertical pyramids or pitted against each other at opposite ends of the quality spectrum (below). Instead, a paradigm shift which accommodates

evaluations of how interventions work in diverse patients and between countries will be more meaningful.

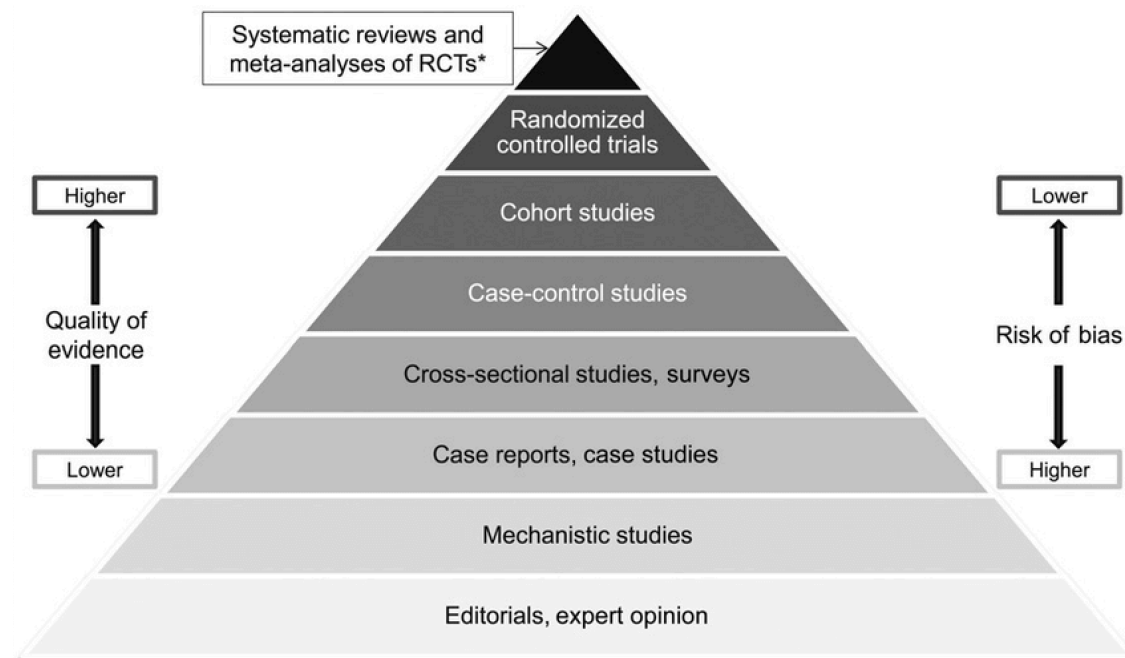


Figure 26: Hierarchy of Evidence Pyramid (ResearchGate 2016).

RCTs can be implemented in a way that findings are likely to be seriously biased and therefore of little value in decision-making (Centre for Reviews & Dissemination 2008) and this flaw should be seriously considered. This is corroborated by Calcagni (2019) who states that research on chronic diseases is already complex as participants (cancer patients) are already weakened, difficult to access and have a high risk of attrition. In some ways, RCTs are compounding the issues they seek to solve and creating stagnation in the evidence base. Higgins (2011) suggests future researchers evaluating RCTs should rely on more solid, complete and recent assessment tool such as the Cochrane risk-of-bias tool for randomized trials (RoB2).

The CONSORT (2010) statement currently suggests that authors should report on the interventions for each group with sufficient detail to allow for replication (Hoffman 2014). However, despite endorsement of the CONSORT statement by many journals, reporting of interventions is deficient. It is difficult to replicate past studies and advance the science when details such as dose, session delivery and protocol details are omitted in reports of intervention fidelity leading to reporting and attrition bias (Sikorskii 2021). Furthermore, without clear recording of individual studies it is difficult to detect performance bias and detection bias. There is also evidence to suggest that failure to report a method does not necessarily mean it has *not* been used (Hill 2002, Devereaux

2004, Soares, 2004). Sikorskii (2009) says that as the number of multicentre trials increase, it is beneficial to include data management and data quality assurance in order to significantly improve the quality of data derived from these trials. It is suggested that exploratory, dose-ranging and efficacy CAM trials utilize high quality methods to ensure the highest degree of standardization possible. The exact meaning of standardization in massage and reflexology research has yet to be clarified. Skivington (2021) tells us that standardisation of interventions could relate more to the underlying processes and functions of the intervention than on one specific form of components delivered (Hawe 2004). For example, in a therapeutic setting there is potential for expectation and conditioning to create the conditions for improving outcomes (Whatley 2023). Thompson & Rossettini (2021) tell us that by employing pragmatic randomised trials researchers can a) define and measure different contextual factors (patients expectations, clinicians beliefs, and patient-therapist verbal and non-verbal communication) and b) use mediation analysis to partition out contextual effects and to represent the specific effects of a treatment (also known as 'natural direct effect'). It is also possible to plan randomised controlled trials where enriched and impoverished contexts are compared. There are potential solutions to understand the 'active ingredient' involved in a positive outcome.

4.5 Template for Intervention Description & Replication (TIDieR)

Hoffmann (2014) tells us that few journals currently provide specific guidance about how to report interventions, so trying to make sense of the literature can be a less than straightforward task. TIDieR has been developed by an international group of experts with the overarching purpose of the TIDieR to engage researchers in rigour by giving details of their interventions can be seen in the checklist. For complex interventions, this detail is needed for each component of the intervention (Hoffman 2014). Recognising massage and reflexology as complex interventions and utilising TIDieR could deepen the knowledge base on the effectiveness of these modalities. Instead of perpetuating similarly flawed studies which are not necessarily replicable or generalisable to other populations, TIDieR may go so far in improving quality of reporting interventions. TIDieR checklist explanation and elaboration here gives examples of how massage and reflexology interventions could be reported.

Figure 27: TIDieR Checklist – Description, Explanation & Elaboration.

TIDieR Item no	Description/Explanation/Elaboration	Example using study...
Item 1: Brief Name	Precision in the name or brief description of an intervention enables easy identification and facilitates linkage to other reports on the same intervention.	<i>The effects of reflexology on anxiety, depression, QoL in gynaecological cancer patients with reference to Watsons Theory of Human Caring.</i>
Item 2: Why (rationale, theory, goal)	Inclusion of the rationale, theory or goals that underpin an intervention, or the components of a complex intervention. The known, or supposed <i>mechanism of action</i> of the active component/s of the intervention should be described.	<i>It is clear reflexology is widely used in experimental research and necessitates further study; Jean Watsons theory emphasises the importance of a holistic approach instead of a task-orientated one to aid the healing process.</i>
Item 3: What (materials)	A full description of an intervention should describe what physical information materials were used as part of the intervention. The list of materials can be regarded as comparable with 'ingredients required for a recipe'. For example, training materials.	<i>Suitable environment; well-lit, warm room; privacy. Theory into practice by using 6 factor healing processes using creative and scientific problem-solving decision making; 'conscious use of touching methods'. Feet warmed for 5 mins; outlines reflexology protocol. Sessions of 45 mins.</i>
Item 4: What (procedures)	Describe what processes, activities or procedures the intervention providers carried out. This item refers to the 'methods section' of a recipe where intervention materials are involved, and describes what is to be done with them. Procedure can refer to steps followed; referral, screening, assessment, education, treatment sessions.	<i>Simple randomisation using statistical package for social sciences (SPSS) independent of researchers. Researchers performed single-blind reflexology & analysed data. Sessions took place after confirming women had not eaten for an hour before session. If medication was used, treatment was delayed. Data collection 1)Personal Info 2) Beck Anxiety Inventory 3) EORTC CORE-30.</i>
Item 5: Who provided (psychologist, nursing assistant)	Who was involved in providing the intervention. Important in circumstances where the providers expertise and other characteristics could affect the outcomes of the intervention. Might include number of providers involved in delivery, their disciplinary background, pre-existing skills, expertise and if and how these were verified.	<i>One provider – Researcher. Not a lot of information.</i>

Item 6: How (modes of delivery – individually or group)	Specify whether the intervention was provided to one participant at a time, to a group and if so, what group size.	<i>Intervention provided one at a time; 62 women. Conducted between October 2016 – June 2018. Oral & written informed consent obtained. Ethical approval obtained from ethics committee.</i>
Item 7: Where (location description)	At simplest level, the location might be for example a participants home, residential care facility, outpatients clinics, inpatients hospital room or combination of locations. Features of the location can be relevant and should be described: country, type of hospital, public or private funded care, details of healthcare system, availability of facilities or equipment. These factors can impact on intervention such as feasibility or participant adherence and are important for those considering replicating the intervention.	<i>University Hospital in Aegeon region, Turkey. No further details on hospital. Study population: ovarian, uterine, cervical cancer patients who received treatment in previous year.</i>
Item 8: When & how much (describe number of times intervention delivered- time period)	The type of information needed about when and how much of intervention will differ according to the type of intervention. For example 'delivered weekly one hour session in home for up to 8 weeks'. Tailoring of the intervention to individuals or groups is elaborated in un item 9. May include detail of timing or intervention in relation to relevant events (how long after diagnosis, first symptoms or crucial even did the intervention start).	<i>Interventions were performed 3 times a week, at one day intervals for each patient. Each patient received 6 sessions in total over a two week period.</i>
Item 9: Tailoring (personalised, adapted)	In tailored interventions, not all participants receive an identical intervention. Interventions can be tailored for several reasons such as; titration to obtain an appropriate 'dose', participants preference, skills or situation or it may be an intrinsic element of the intervention as with	<i>Tailoring included; delaying treatment if analgesic or anti-emetic drugs were consumed. Lack of information on whether treatments were standardised or not.</i>

	increasing intensity of an exercise. Hence, a brief rationale and guide for tailoring should be provided including any variables/constructs used for participant assessment.	<i>No clear information was provided on how Watsons Theory of Human Caring was implemented or adapted in the study. This area will be important in 'whole-systems approaches'.</i>
Item 10: Modifications (describe changes)	This refers to modifications that occur at the study level (what, why, when & how). Not individual tailoring as described in item 9. Modifications sometimes reflect changing circumstances. In other studies they show learning about an intervention which is important to transmit to the reader to prevent unnecessary repetition of errors during attempts to replicate intervention. Changes to intervention between published protocol or pilot study and primary paper should be described.	<i>No information on adaptations to the protocol other than those general statements relating to medication and food. This area will be relevant in 'whole-systems approaches'.</i>
Item 11: How well (planned).	Fidelity refers to the degree to which an intervention happened in the way the investigators intended it to and can affect the success of an intervention. Terms used to describe this concept vary among disciplines including; treatment integrity, provider or participant adherence and implementation fidelity. In complex interventions such as rehabilitation, psychological or behaviour change interventions assessment of fidelity is more complex. Strategies and tools to maintain fidelity should be clearly described.	<i>Lack of information. Recommendation made that nurses 'use the theory of the core processes to plan more RCTs'.</i>
Item 12: How well (actual)	An intervention or part of it may not be delivered as intended, thus affecting the fidelity of the intervention. Authors should describe the extent to which the delivered intervention varied from the intended intervention.	<i>Lack of information regarding safety aspects & monitoring. 'The patients in the present study did not experience side-effects. However, it should be kept in mind in further research there may well be'.</i>

Figure 27: *TIDieR Checklist Explanation and Elaboration using example study (Hoffman 2014). Study: Turkeu & Ozkan (2021).*

4.6 Complex Interventions

Interventions such as massage and reflexology are complex interventions made up from a number of components, which act independently and inter-dependently (Craig 2008). Reflexology has grown into a complex therapeutic modality in its own right (Whatley 2023). By definition, integrative therapies are personalised to the individual. This makes intervention standardization a challenge for integrative oncology research (Mao 2019). However, research typically involves a standardized intervention that can be tested across a diverse population so that findings can be easily replicated, generalised to large patient groups and ultimately implemented in a standardized manner. As we can see from included studies, standardization of massage and reflexology becomes more challenging in cases where carers are used after minimal training and or the principal researcher has trained only for the purposes of the study. It could be argued that standardization of interventions are only appropriate when carried out by qualified practitioners because the underlying premises of the therapies are understood and potentially enhance the overall benefit of the intervention treatment. There is some evidence in the studies of attempts to standardize treatment (Wilkie 2000; Tarrasch 2018; Murat-Ringot 2021; Lopez 2022).

4.6.1 Effectiveness & Efficacy Studies

Studies within massage and reflexology in oncology settings can be considered to be in a state of flux. As understanding of research and the subject matter evolves, a shift in focus from efficacy to effectiveness is becoming visible in the literature future directions. In other words, the presence of the pragmatic paradigm is stronger; *relational epistemology* where relationships are determined by what the researcher deems appropriate; *non-singular reality ontology* where there is no single reality; *mixed methods methodology* and a *value-laden axiology* (Kivunja 2017). The latter is the driving force within CAM which is conducting research which *benefits* people and is inextricably linked to social justice.

Perspective and research question	Key points	Vaccine study example
Efficacy		
To what extent does the intervention produce the intended outcomes in experimental or ideal settings?	Conducted under idealised conditions; maximises internal validity to provide a precise, unbiased estimate of efficacy	Seeks to measure the effect of the vaccine on immune system response and report its safety ²⁸
Effectiveness		
To what extent does the intervention produce the intended outcomes in real world settings?	Intervention often compared against treatment as usual; results inform choices between an established and a novel approach to achieving the desired outcome	Seeks to determine whether the vaccination programme, implemented in a range of real world populations and settings, is effective in terms of what it set out to do (eg, prevent disease) ²⁹
Theory based		
What works in which circumstances and how?	Aims to understand how change is brought about, including the interplay of mechanisms and context; can lead to refinement of theory	Asks why effectiveness varies across contexts, and asks what this variation indicates about the conditions for a successful vaccination programme ³⁰ ; considerations that might be explored go beyond whether the vaccine works ³¹

Figure 28: Perspectives & research question. (Skivington 2021) A new framework for developing and evaluating complex interventions: Update of Medical Research Council Guidance.

It is accepted that some questions cannot be answered by research restricted to an efficacy or effectiveness perspective. Instead, a wider range of research perspectives need to be used by researchers and supported funders. This would help answer other important questions for decision makers such as: *What does the existing evidence suggest is the best option now and how can it be evaluated? How are the intervention effects mediated by different settings and contexts?* For example, Skivington (2021) says that programme theory which describes how an intervention is expected to lead its effects and under what conditions, is an important evaluation outcome. It is the principal aim where a theory-based perspective is taken, and this gets to the heart of where the evidence base is currently lacking within massage and reflexology.

Future researchers in CAM should consider the framework (below) and engage stakeholders in order to develop interventions, implement and evaluate. Evaluation may point to other methods such as observational studies, reflecting what is called 'real world' practice (Grant 2022).

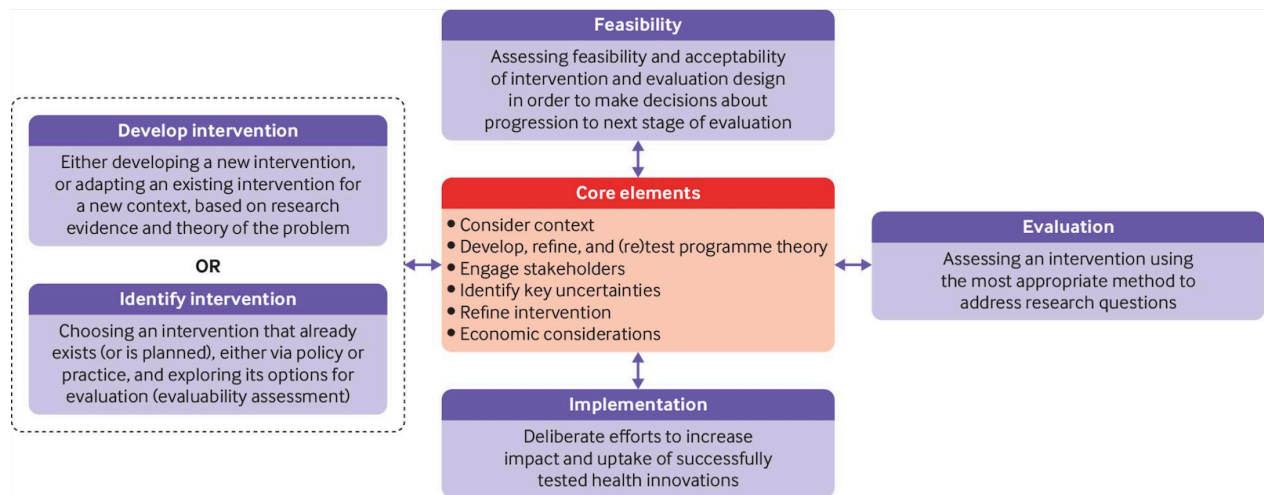


Figure 29: *Framework for developing complex interventions.* (Skivington 2021) A new framework for developing and evaluating complex interventions: Update of Medical Research Council guidance.

4.7. Measurement Tools

Defining and measuring the quality of life of people living with and beyond cancer is not straightforward. Jolliffe (2015) tells us while there is a plethora of tools to assess and measure patient reported outcomes, there are very few that are being used in the research that fully represent all the items important to patients. There are questions regarding the reliability, validity and acceptability of many of these tools.

FACT-G is a 27-item generic health-related quality of life (HRQL) measure that has been widely validated (Cella 1993). More recently, FACT-G was the only tool to receive a 'sufficient' rating for content validity (Mitchinson 2022). EORTC QLQ-C30 is a 30-item cancer specific health-related quality of life measures that has also been widely validated (Groenvold 1997). The Impact of Cancer V2 (IOCv2) has good reliability and is deemed applicable to UK populations. A number of strengths have been identified with the Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being (FACIT-Sp) and it appears to be a brief, reliable measurement that may be useful in assessing the role of nonreligious spirituality in quality of life research (Peterman 2002).

However, finding the right tools to measure various aspects of health & wellbeing may not be as important as recognising the value of evidence from a diversity of approaches (Price 2014). Instead of the employment of multiple varied measurement tools within randomized controlled studies, integrating data from different study designs may be more fruitful. Price (2014) says that it is possible to get a fuller picture

of the utility of an intervention by drawing on different study designs and analytical approaches. Approaches combined together make good of each other's deficiencies and better accommodate the circumstances under which the treatment is practiced.

4.7.1 Observational & Pragmatic Studies

Price (2014) suggests resorting to 'real life' studies when the RCTs show their limits. Thus, observational studies (cross-sectional, cohort) and pragmatic trials (real life context of clinic) could prove complementary when assessing questions that are 'unanswered' or 'unanswerable' by RCT. Price (2014) states that pragmatic trials have the benefit of evaluating the effect of interventions over a more appropriate period of time than is feasible for an RCT. Inadequate length of studies and follow-up is a prevalent weakness in the literature, so such a design could prove to be a valuable asset in evaluating interventions of massage and reflexology. Although observational studies are limited in the extent to which they can demonstrate cause and effect, and missing data can limit interpretations, validity can be strengthened by certain measures.

The experimental single-case research design may also have something to offer studies in massage & reflexology because this is one of the most cost-effective and efficient procedures to experimentally test the effect of an intervention (Smith 2012). Figure 30 shows how 'real life' studies (pragmatic & observational) can help to inform the objectives of classical randomized clinical trials.

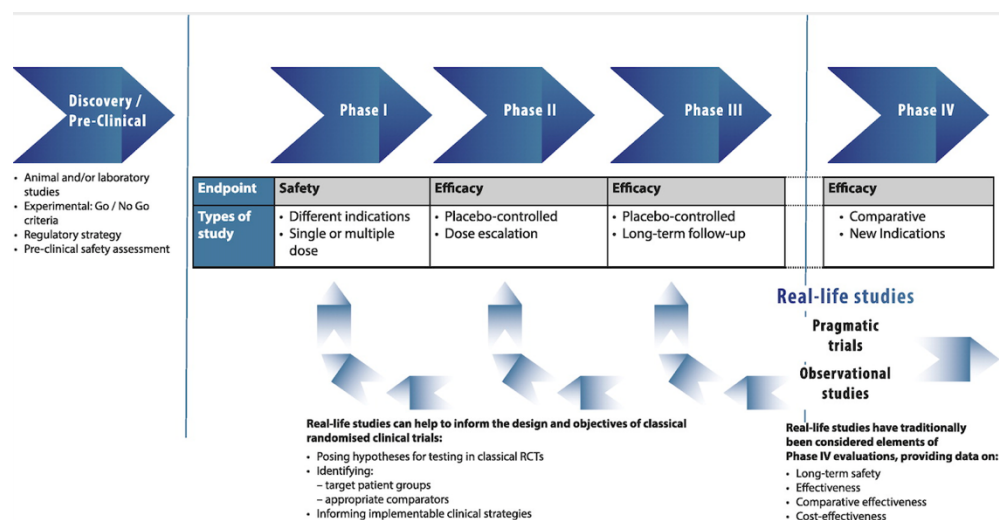


Figure 30: *Illustration of how real-life studies can build on existing evidence and also feed earlier phases of research.* (Price 2014) Complementing the Randomized Controlled Trial Evidence Base. Evolution Not Revolution.

Essentially pragmatic and observational studies can validate RCTs findings and work in a complimentary, integrated way while evaluating the longer-term effects, contextual effects, comparative elements and cost-effectiveness. All of these featured as recommendations as future study priorities in the studies of this systematic review.

4.8 Education & Research

Perhaps one of the most disappointing findings in the literature was the heterogeneity in terms of care-giver/practitioner. The fact that 22.9% of the studies were carried out by the principal investigator and 33% do not refer to credentials or experience of the provider is poor. This reflects the poor research culture and inherent barriers. Barriers to research can be categorised into those associated with knowledge & skills, capacity, collaborative opportunities & funding (Veziari 2021).

The impact of funding has been widely reported in the literature. Research funding schemes are not currently designed to support CAM research (Veziari 2021). Furthermore, there is a perceived bias in terms of access to research funding for CAM, attributed to the non-recognition of CAM as a research priority, limited understanding of CAM research and hence negative attitudes of grant reviewers (Nahin 2001; Bensoussan 2004; Wardle 2013).

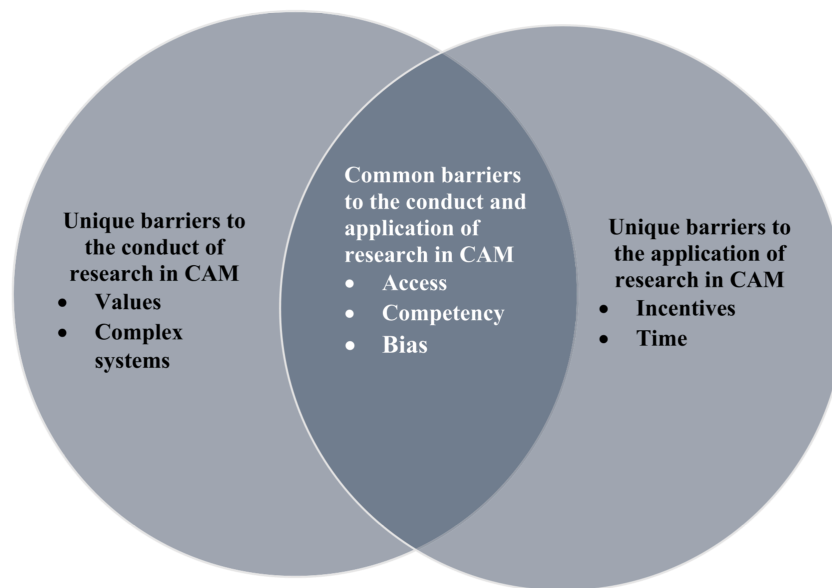


Figure 31: Overview of the common & unique barriers to the conduct & application of research in CAM. Veziari (2017). Barriers to the conduct and application of research in complementary and alternative medicine: a systematic review.

4.9 Conclusion

This systematic review has aimed to distinguish between studies which include complementary therapies as an overarching topic compared to a focus on massage and reflexology studies. Important aspects of methodological quality show weaknesses such as allocation concealment, blinding, statistical analysis is common, as is failure to report sufficient detail about an intervention and its implementation.

Utilization of the TIDieR template has potential to enhance our understanding of the current research and draw out themes which can improve the research base. One current theme is the conceptualization of massage and reflexology as 'complex interventions'. For example, a variety of contextual factors including the therapeutic relationship and psychological support embedded within the holistic approach. Authors might want to be guided by the TIDieR items when describing interventions in systematic reviews so that readers of reviews have access to full details of any intervention that they want to replicate after reading the review (Hoffman 2014).

Veziari (2021) says that even though complementary therapies have long valued empiricism, philosophical and cultural differences have resulted in many CAM stakeholders being opposed to the evidence-based movement. The constraints which have been placed on evidence-based practice within complementary therapies needs

to be addressed, bringing these small pockets of CAM research together and making sense of the findings. This means advancements in education and the research culture within CAM itself; raising the profile of evidence based practice. Parallel to building a research culture, is the need to devise frameworks that unite, rather than segregate different streams of research. At the same time, accessing the research resources and funding is a top priority.

Chapter 5 Conclusion

5.1 Conclusion & Recommendations

5.2 Mental Health & Spirituality

As we have already established, not only the physical health of patients, but their mental health can be significantly affected by a diagnosis of cancer (Zhang 2015). Much research have shown that the most common psychological states with cancer patients are anxiety and depression (Cassileth 2004; Edman 2014; Samuel 2014; Wu 2015; Donoyama 2018). The mixed symptomology is very common with two-thirds of cancer patients with depression also expressing clinically significant levels of anxiety (Brintzenhofe-Szoc 2009). Wanchai & Armer (2020) systematic review says that reflexology was reported to improve quality of life, reducing fatigue, nausea and vomiting but less clear outcomes for depression and anxiety. These findings are generally consistent with this systematic review.

Qin (2020) points out that massage is widely used due to its non-invasive, safe and inexpensive features. Similarly, reflexology studies report positive psychological aspects such as quality of life and reduced nausea and vomiting, all of which contribute to mental health. Massage is one of the most widely used complementary therapies that not only relieves cancer-related symptoms such as fatigue, pain and anxiety (Wilkinson 2007; Ernst 2009) but also brings physical and mental pleasure (Wilson 2018). Liu (2022) meta-analysis writes that massage therapy is an effective alternative for pain control. However, more high-level evidence is needed (Wanchai & Armer 2020).

Fatigue appears to be understudied with regards to post-traumatic growth in cancer survivorship yet is a dominating theme in the massage and reflexology literature. Miller (2022) writes that spirituality often becomes especially salient when one is faced with cancer, and a sense of spirituality can support psychological adjustment to cancer (Stenhauser 2017). Yet this subdimension appears to be less important at least in

western countries (Holtmaat 2017). Spirituality studies and cancer survivorship are in their infancy in the literature base.

At present, pharmacotherapy and psychotherapy, the main treatment means for anxiety and depression in cancer survivorship, play an important role. However, antidepressants and anxiolytics may bring a variety of adverse impacts such as headaches, addiction, seizures, suicide and interactions with anticancer treatments (Desmarais 2009). At the same time, psychological interventions are often limited due to lack of providers and financial resources (Okuyama 2017). It is a necessity to seek alternative treatment that is effective, cheaper and safer.

5.2.1 Recommendations

Along-side larger studies on depression and anxiety, the understanding of fatigue mechanisms that lead to post-traumatic growth are welcomed. Furthermore, there is an identified need for evaluating spirituality's role in experiences of pain including visceral, neuropathic, central sensitization (Miller 2022). Spiritual distress is an area worthy of future study in cancer related symptoms (Miller 2022). Miller (2023) study also highlights the value of further integrating spirituality into palliative care and points out that additional research is needed to explore how broad aspects of spirituality may be harnessed as part of comprehensive symptom management.

Current data suggest that massage may have benefit as an adjuvant to conventional care. Rapaport (2018) contends that approaches to identifying potential treatment interventions for patients needs to be broadened. A model of how psychiatrists, oncologists and other mental health professionals can work with massage therapists is suggested. For example, collaboration between psychiatrists and massage therapists could capitalise on the benefits of *both* forms of treatment. There are numerous ways to approach this within the research on massage and reflexology; incorporate psychiatric support into the RCT research design as a comparative arm, or within a pragmatic trial assessing interventions holistically through observation and comparison.

This points towards a whole-system approach and development of new interventions which combine psychiatric and physical therapies and could enable the testing of theories, based on current research. This involves integrating the current evidence on massage, reflexology from randomized controlled trials and including psychiatric data to date. As chapter four explained, real-life studies can inform and validate RCTs and at the same time evaluate and compare more effectively, including the safety aspects of treatments. Jahani (2018) recommends further research on the effect of reflexology on pain and anxiety of *other* patients, ie non-cancer patients, but who experience pain as the symptomology of their condition. Pain is an especially interesting area for future research within massage and reflexology. As Lee (2015) writes massage has significant effects for cancer relief, larger well-designed studies with appropriate sham are needed with longer follow-up in order to draw firm conclusions.

5.3 Mechanisms of Action – Massage & Reflexology

Rigorous study of the biology of therapeutic massage and reflexology is still in a relatively nascent phase. Data does suggest that massage may be associated with a decrease in hypothalamic-adrenal activation and possibly with an increase in oxytocin levels (Rapaport 2012). The brain stimulated by c-fibres is associated with feelings of well-being; massage also stimulates brain circuits involved in the control of sympathetic and para-sympathetic activity, with an enhancement of parasympathetic tone; this could lead to a decrease in stress response, and modulation of certain aspects of immune function. It is therefore possible to synthesize the existing data regarding the biology of massage into a cogent working hypothesis about its benefits for certain psychiatric disorders (Rapaport 2018). Furthermore, although data on the impact of massage on EEG and neuroimaging changes to the brain are limited, when combined with data on somatic sensory pleasure circuitry (affective touch), it is reasonable to postulate that massage's beneficial effects on affiliation and feelings of well-being may be due to stimulation of specific brain circuits involved in pleasure and reward (Lloyd 2015). It is unclear whether the therapeutic benefits of massage occur as a result of manipulation of muscle or through the brain as a result of interaction with the subcortical components of the nervous system (Sagar 2007).

Much of the ambiguity in the reflexology literature seems to stem from a limited understanding of the physiological and biochemical mechanisms underpinning reflexology (Tian 2023). While it is important to consider aspects of touch, placebo and contextual factors, the role of fascia should be given consideration as a potential theory of mechanism for the deeper manipulative techniques of reflexology treatment; maintenance of structural integrity in the musculoskeletal system and the potential impact on pain modulation, fluid movement and cellular activity (Whatley 2022). Further research is therefore recommended into the activation of fascia from the reflex points of the foot and ankle.

5.3.1 Recommendations

Some examples of progress to identify other impacts include the development of a robotic device engineered to deliver the same amount of pressure on reflexes (Flynn 2011). There is also a plan to investigate the relationship between nausea, vomiting and reflexology at cerebral level using functional magnetic resonance imaging (Murat-Ringot 2021). Whatley (2022) tells us that the recent research in fascia has implications for reflexology studies, because the relationship between mechano-transduction and cellular response involves the connection between different cell types, proteins and pressure. Early evidence has shown that applied pressures in reflexology may have a definitive benefit for health and wellbeing. Such studies may go some way in terms of assessing value of both massage and reflexology.

Anderson & Downey (2022) also recommends improving the research by studying the effects of reflexology on *other* populations separating symptoms, identifying sub-types of pain, but also examining the differences between reflexology practitioners. Ozdelikara & Tan (2017) recommend the study of quality of life among persons with different types of cancer and with specific symptoms. Sikorskii (2021) who conducted multi-symptom research recommends that reflexology is further tested for symptom palliation among those with the highest symptom burden. The science and design of evaluation symptom management still often focuses on single symptoms. In common with RCTs this approach has several drawbacks, one of which includes a barrier to personalised tailoring of symptom management interventions (Sikorskii 2021).

The data suggests there is a parsimonious way of conceptualizing the mechanisms underlying its beneficial effects (Rappaport 2018). Lack of consistent funding for the investigation of massage is a significant challenge to be addressed. One of the ways which this could be addressed is by considering cost-effectiveness studies. Cost-benefit analyses of the impact of complementary therapies such as reflexology should be developed to capture the broad picture, both in the immediate aftermath of treatment and later on (Whatley 2022).

5.4 Methodological Problems and Risk of Bias (RoB)

One of the most significant challenges in the field are the many types of massages and the variation of research study designs. This means that current knowledge of both massage and reflexology rests on a number of small studies investigating very different interventions that have been done for different lengths of time and at different frequencies (Rapaport 2018). There are a number of methodological concerns regarding blinding of participants, the heterogeneity of interventions, participant characteristics and outcomes, resulting in a low to 'very low certainty of evidence' in terms of randomised-controlled trials.

The applicability and generalisability of study results to wider populations and contexts are limited (Tian 2023). Difficulties with blinding is a by-product of the hands-on nature of massage and reflexology. Between-group comparators also exhibits heterogeneity where effects of massage or reflexology were compared to 'usual care' or a range of other control groups. As Tian (2023) states, comparisons between for example, reflexology and 'usual care' or 'other intervention' reveals mixed findings. This heterogeneity is visible in the included RCTs in this systematic review. Few studies have reported attempts to identify clinically relevant massage therapy frequency and doze, however the positive effects of massage have been reported to be sustained for at least a week after the session, and longer follow-up periods are needed (Rapaport 2012). Liu (2022) recently noted that there are about 100 different forms of massage therapy in clinical practice that need to be subjected to fair comparison among studies to test the consistency of their efficacy (Ezzo 2007).

5.4.1 Recommendations

While accounting for the fact that research findings cannot be generalised, it is possible to build on the research findings along with their inherent limitations. Liu (2022) says that due to the popularity of massage therapy, blinding is impossible, so *unblinded* practical trials are recommended because they are applicable in the real world and can be used to increase external validity. Future research could build on Mantoudi's (2020) study, which compared two therapies not directly attempted before in a palliative setting. In pragmatic and observational studies of the two comparators, elements such as effectiveness and comparative effectiveness and cost-effectiveness can be evaluated as an extension of previous work. Target populations and settings could also be assessed, in order to widen the scope (and external validity) of research while building on randomised-control trials initial findings. Sharp (2010) recommends to evaluate the relative contributions of extra physical contact and extra social contact. While Fernandez-Lao (2012) states that the 'placebo' effects associated with hands-on techniques cannot be excluded, which in itself, is capable of eliciting autonomic nervous system responses. Black (2009) tells us that the placebo needs to be viewed as an integral part of the treatment rather than an aspect that should be isolated and discounted. In addition, incorporating the *patient voice* throughout development may help bridge the gap between patient experience and clinical trials (Mitchinson 2022). Lopez (2022) concluded that dose-intensity was more important than location, while authors recommend testing the cumulative effects of treatment over longer periods of time. Future RCT planners should learn from previous studies, which support further investigation into the *cumulative* effects of massage and reflexology (Turkeu & Ozkan 2021).

Pragmatic and comparative effectiveness trials provide one solution to some methodological concerns such as blinding, but do not address the underlying limitations such as optimizing protocols (Porcino 2013). This calls for a sharper focus on contextual assumptions, such as how massage, massage therapy, therapeutic massage and the various types of reflexology are defined within the scope of *each* study. Not addressing assumptions will limit the transferability and generalizability of research results, as well as efforts in knowledge translation and clinical adaptation. Porcino (2013) points out that there are few studies which compare strengths and weaknesses between different types of techniques, even though they may be

mechanistically similar or used to achieve similar outcomes. One such example of massage variation is the Donoyama (2018) study where the method of 'Japanese massage' (AMT) techniques are used. The use of appropriate reporting guidelines such as the Template for Intervention Description Replication (TIDieR) checklist and guide to facilitate standardised reporting of intervention parameters. and replication (Hoffman 2014).

5.5 Complex Interventions & Safety

Skivington (2021) writes that complex intervention research goes beyond asking whether an intervention works in the sense of achieving its intended outcome to asking a broad range of questions; identifying what *other* impact it has; assessing its value relative to resources required for delivery; theorising *how* it works; taking account of how it works in the *context* in which it is implemented; how it contributes to system change *and* how the evidence can be used to support real-world decision making. In terms of theorizing how massage and reflexology work, it is important to consider the role of ritual & placebo. As Black (2009) writes, the placebo effect can also be considered in broader terms as a contextual effect reflecting the contribution that the context of the intervention makes to its effect. For example, Fernandez (2012) showed how the positive impact of massage on cancer-related fatigue (CRF) is modulated by the *attitude* of the patient towards the massage.

Serious CAM-related risks appear to be rare. Researchers need to determine whether they should pursue a search for harmful components or address safety at a systematic level. Even those CAM practices and products which are regulated rarely have adequate systems in place for reporting, assessing and acting on harmful incidents (White 2014). This presents an opportunity for better safety surveillance embedded into future designs of both massage and reflexology research.

5.5.1 Recommendations

Skivington (2021) says that for complex interventions to be most useful to decision-makers, it should take into account the complexity that arises both from the intervention's components *and* from its interaction with the context in which it is being

implemented. There is a strong case for renewing the state of knowledge around placebo and context to devise a more systematic approach to the generation of knowledge in this area. More rigorous study into placebo and contextual effects within complex interventions offers an opportunity for learning which can be applied to *both* complementary therapy practice and orthodox practice (Black 2009). The overall effect of massage therapy may depend on the practitioner, so the qualification, experience and clinical expertise. The current lack of uniformity in practitioner's indicates an area requiring attention. TIDieR will assist in recording of these details in future.

A specific challenge will be to develop methods to circumvent the complacency among some CAM traditions with regard to potential harm of their treatments. One way to do this is the implementation of TIDieR in future research in massage and reflexology. This could include reference to a 'healing crisis' in the research. There are only a few examples of research into this concept (Stub 2012) although the phenomena has been reported for centuries (Makereth 1999).

5.6 Measurement Tools

Determining how best to measure quality of life in people with cancer and beyond into survivorship is of paramount importance to ensure the best approach to screening and assessing the effectiveness of interventions. Mitchinson (2022) carried out an extensive search of published literature identified tools used in evaluation of massage and reflexology in a broad range of clinical populations. Poor quality ratings were common as a result of small sample sizes. This is common within palliative care for a number of reasons; participants are difficult to recruit; poor health cognitive impairment or gatekeeping and a greater rate of attrition due to deterioration and death.

Moschopoulou (2021) shows us that FACT-G and the EORTC QLQ-C30 (see extraction forms for use in research) are measuring similar aspects of quality of life and are equally pertinent and easy to use. Findings suggest that the Impact of Cancer V2 (IOCv2) captures a unique aspect of quality of life over other measures, focusing on the positive and negative impacts of cancer associated with long-term survivorship (Stanton 2006). This is important in relation to post-traumatic growth and future research; positive impact of cancer reflects a less understood area of cancer enquiry.

5.6.1 Recommendations

The evidence quality of measurement tools studies is affected by the limited number of studies evaluating psychometric properties (Mitchinson 2022). Many studies of the role of spirituality in living with cancer have employed measures whose reliability and validity have never been established (Peterman 2002) and are not visible in the body of evidence in this systematic review. This dearth of close evaluation of individual tools presents an opportunity for future researchers, and thereby increase the overall value of the evidence base on massage and reflexology. Further qualitative ways to explore mechanisms of impact will be helpful. Understanding which outcomes are the most important to assess will enable effective targeting of future research. Mitchinson (2022) says that the development of a core outcome set for complementary therapies is essential. By consulting patients, therapists and academic field experts, a consensus can be reached to agree on core outcomes. Until a more comprehensive and valid outcome measurement tool is developed, the Functional Assessment of Cancer Therapy – General (FACT-G) is provisionally recommended for use in future trials with people living with advanced disease (Mitchinson 2022). Moving forward the research in CAM, the use of validated measurement tools is important for cost-effectiveness studies in naturalistic trials.

5.7. Cost-effectiveness

Black (2009) states, given the limitations of the evidence base, commissioners may want to consider commissioning complementary practice alongside robust evaluations or research trial to assess effectiveness. In the last decade, researchers have improved the methods for design, conduct and analysis of data for economic evaluation alongside clinical trials. What is more, the increasing numbers of randomized trials that evaluate comparative effectiveness in clinical practice, for example using data from patient registries provides new opportunities for economic evaluations alongside RCTs (Ramsey 2015).

It is generally acknowledged that pragmatic effectiveness trials are the best vehicle for economic studies. When designed, analysed and interpreted appropriately, economic

evaluations alongside randomized clinical trials are important sources of information for decision makers. To be useful as a stand-alone evaluation, a trial must be designed to represent the population, duration of treatment, clinical practice, types of outcomes and other factors most relevant to the clinical situation to which the decision is to be applied (Ramsey 2015). The external validity of research designs can be increased by designing trials which are naturalistic and designed to evaluate the effectiveness of interventions in real-life practice conditions (Drummond 2005).

5.7.1 Recommendations

New research methodologies in massage and reflexology which are sympathetic to the real-life context will be conducive to the cost-effectiveness analysis needed to improve the research. Interestingly, clinical end points that focus on the impact of a treatment on how a patient feels, functions and survives are most useful for economic evaluation (Ramsey 2015). This focus is possible to achieve with pragmatic, observational studies which have qualitative data embedded. Finally, carrying out cost-effectiveness analysis will estimate costs, cost differences associated with treatment (comparator) variability of differences and whether the differences occurred by chance (Ramsey 2015). This highlights two important factors: a) the importance of selecting an appropriate comparator treatment in CAM and b) how cost-effectiveness research can elucidate more information from a study relating to chance as opposed to effectiveness.

Approaches such as system-wide trials of care pathways that included complementary practice, where possible in comparison with established pathways would test for different patterns of service to show reduced costs or deliver better health outcomes. This work could precede and inform more detailed studies of effectiveness and mechanisms of action. Moreover, funding could be conditional on it being part of such comparative research (Black 2009).

5.8 Limitations

The main limitation of this systematic review was the restricted access to journal articles found within specific journals. A number of unsuccessful attempts were made

to gain access to up-to-date studies found within the *Journal of Alternative and Complementary Medicine*. In addition, given the historical eastern origins of massage and reflexology, studies in other languages have not been included in this systematic review.

This systematic review calls on all complementary practitioners to accept their vital role of evidence in the development of their practice and not to assume effectiveness without understanding the research base.

6. Reflective Account

The preparatory stages of formulating the dissertation question and refining a proposal proved to be a useful learning experience. The adoption of systematic methods in terms of documentation and time management was invaluable, as well as the necessity of taking advice from the academic tutor.

A period of work experience was gained. The experience reflected the literature base including the need for expanding research practice. A highlight of the year was attendance at 'The Essence of Aromatherapy Seminar' in May at the Royal Botanical Gardens, Edinburgh. As a result, connections with leading educators in complementary therapies has opened training opportunities in 2024.

In November 2023, an application was made to the Churchill Fellowship.
www.churchillfellowship.org

6.1 Continuing Professional Development

- 1) On-line Masterclass 'The Importance of Feet in the Fascial System'. Osteopathic Reflexology Approach (ORA) by Florence Cohen. Reflexology Academy. Thursday 22nd February 2024. Available from <http://www.reflexologyacademylondon.com/courses/cpd-advanced/osteopathic-reflexology>
- 2) Kinetic Chain Release Training by Alex Bairnstow. February 2024 (date to be confirmed). Available from <https://www.bodyworksbodywise.co.uk>
<https://www.kcracademy.com>
- 3) AquaCare Masterclass by Madeleine Kerkhof. 6-9th June 2024. Netherlands. Available from <http://www.kicozo.info/aquacare-masterclass-in-the-netherlands/>
- 4) Oncology Skincare Course by Fiona Shannon. 2024. London (discussed in person at seminar and via email – to be confirmed).
- 5) Opportunity to gain work experience in 2024 at Guy's Cancer Centre, Guy's Hospital. London (discussed in person at seminar and via email with Emma Tyrer).
- 6) The Essence of Aromatherapy Seminar. Attended in May 2023 <https://clinical-aromatherapy.vfairs.com/>

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American Cancer Society. <http://acsjournals.com>

American Massage Therapy Association. <https://www.amtamassage.org/>

British Association for Holistic Medicine & Healthcare. <https://bhma.org/>

Complementary & Alternative Medicine for Cancer. CAM Cancer Database.
<https://cam-cancer.org/en/cam-cancer-database>

Cochrane Collaboration. <https://www.cochrane.org/>

Centre for Global Health. <http://www.cancer.gov/about-nci/organisation/cgh>

Cancer Research. <https://www.cancerresearchuk.org/>

Complementary and Natural Healthcare Council. <https://www.cnhc.org.uk/#gsc.tab=0>

Global Cancer Observatory. International Agency for Research on Cancer.
<https://gco.iarc.fr/>

Mayoclinic <https://mayoclinic.elsevierpure.com/>

Meaningful Measures. <https://www.meaningfulmeasures.co.uk/>

The Memorial Sloan-Kettering Cancer Centre: Integrative Medicine Service. New York.
<https://www.mskcc.org/cancer-care/diagnosis-treatment/symptom-management/integrative-medicine>

National Centre for Research Methods. <https://www.ncrm.ac.uk/>

Neuro affective touch. www.NeuroaffectiveTouch.com

NIH National Cancer Institute. OCCAM. Office of Cancer Complementary and Alternative Medicine https://cam.cancer.gov/research/research_results.htm

Norway's National Research Center in Complementary & Alternative Medicine. NAFKAM. <https://nafkam.no/en/research-and-development/research-nafkam>

Oncology Nursing Society. <http://www.ons.org>

PROSPERO. An International Prospective Register of Systematic Reviews. <https://www.crd.york.ac.uk/prospero/>

Podcasts. <http://ascopost.com/podcasts>

Publisher of Open Access Journals. <https://www.mdpi.com/>

Research Council for Complementary Medicine. <https://www.rccm.org.uk/>

Semantic Scholar. <https://www.semanticscholar.org/>

Scite Smart Citations. www.scite.com

Tiffany Field Touch Research Institute. Available from [https://med.miami.edu/centers-and-institutes/mailman-center/community/other-community-based-programs/touch-research-institute-\(archives\)/research](https://med.miami.edu/centers-and-institutes/mailman-center/community/other-community-based-programs/touch-research-institute-(archives)/research)

The British Complementary Medical Association. <https://www.bcma.co.uk/>

UK Research & Innovation. <https://www.ukri.org/>

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