CEU Article Summer 2015

Evidence Based Practice (continued from InTouch Summer 2015)

FLYNN L.L., BUSH T.R., SIKORSKII A., MUKHERJEE R. & WYATT G. (2011) *European Journal of Cancer Care***20**, 686–696

Understanding the role of stimulation in reflexology: development and testing of a robotic device

Reflexology is a common choice of women with breast cancer as supportive care during treatment. It involves stimulation of specific locations of the feet called reflexes using a specialised walking motion with the thumb of the reflexologist. Reflexology has shown potential for the successful management of cancer and treatment-related symptoms and improvement in physical functioning; however to date, the mechanism of action for these improvements is unknown. One confounder to the study of reflexology is the 'human factor'. To study the effects of the stimulation of the reflexes independent of the 'human factor', there is a need for an alternative method for the delivery of reflexology. The objective of this work was to design and create a robotic reflexology device that would deliver a breast cancer-specific reflexology protocol to the feet of patients. A prototype robotic reflexology device was developed and tested for feasibility, safety and acceptability with breast cancer survivors (*n*= 13), and preliminary efficacy in symptom management and enhanced functional status with a sample of women undergoing chemotherapy for breast cancer (*n*= 13). Safety, feasibility and acceptability were established, and significant improvements from pre- to post-device-delivered reflexology were seen in symptom severity among women on chemotherapy.

- **Notes:** *n = number in a trial or sample. We will review a number of terms shortly.*

Some questions came to mind after reading this study. While I've never thought to control the variable of the "human" element, I do find it interesting that even then, the points provided relief. It is unfortunate that the population size was so small. Without a large body illustrating the same results, it's not reasonable to make a global claim. It is encouraging however, and something we can use as a toe hold and even improve upon ourselves, but I'll make my case for our involvement later.

If we wanted to replicate this study, what else would we need to know?

- Protocol used (treatment sites)
- Duration of treatment
- Frequency of treatment
- What symptoms were evaluated relating to their pain to come to an "improvement"? Range of Motion? Swelling? Activities of daily living? Mood? Sleep quality?
- Was a pain scale used? If not, what was the measurable scale they utilized?
- When they evaluated feasibility, was this treatment cost, frequency? What was the feasibility evaluation?

How did you feel about the idea they only addressed certain areas in their reflexology protocol? Did you find this at odds with the principle reflexology treats the whole? How would you address this if they were variables in your own study?

Research Literacy

The more familiar you become reading research the better you become at picking out statements that are misleading.

Take this example

> *In total, therefore, the size of the intractable pediatric epilepsy population is 93,200 patients in the United States and 153,000 in Europe***.**

What is your conclusion? That Europe has a higher patient rate than the US? Wait a second. Let's look at that. Europe's 2013 population is 742.5 million while the USA's the population for the same year is 318.9 million. When compared by percentage, the USA has a higher rate of pediatric epilepsy, but that's not how it sounds based on how they presented the information. This sort of posturing is done with numbers around attrition rates as well. An attrition rate is the dropout rate in a study. Let's say they started with 100 but were left with only 5 who actually completed the study. These numbers can sometimes be hidden, to make the study appear more solid than it is.

Terms

- **Attrition** The loss of participants during the course of a study
- **Heterogeneity** used in a general sense to describe the variation in, or diversity of, participants**,** interventions**,** and measurement of outcomes across a set of studies, or the variation in internal validity of those studies.
- **MeSH** (Medical Subject Headings) is the vocabulary thesaurus used for indexing articles for PubMed
- **N =** number in a trial or sample. Larger samples increase the chance of finding a significant difference, but larger samples cost more money.
- **N-RCT Non-randomised study**
  Any quantitative study estimating the **effectiveness** of an **intervention** (harm or benefit) that does not use **randomisation** to allocate units to comparison groups There are many

possible types of non-randomised intervention study, including **cohort studies**, **case-control studies**, **controlled before-and-after studies**

- **Peer-reviewed** articles have been evaluated by several researchers or subject specialist in the academic community prior to accepting it for publication.
- **Qualitative** – subjective comments "I feel better", can be harder to prove and measure objectively.
- **Quantitative** – more objectively measurable "1 cm reduction of swelling measured at the malleoli (ankle bones) post treatment bilaterally."
- **RCT –Randomised controlled trial**s are an experiment in which two or more interventions, possibly including a control intervention or no intervention, are compared by being randomly allocated to participants. In most trials one intervention is assigned to each individual but sometimes interventions are assigned within individuals (for example, to different parts of the body).
- **Statistically significant** A result that is unlikely to have happened by chance. The usual threshold for this judgement is that the results would occur by chance with a probability of less than 0.05.

Why should we bother becoming more research literate? We have clients consulting "Dr. Google" much more frequently, and our ability to critically read the data being placed before us allows us to better inform ourselves, and also our clients. A case study of one participant who touts findings that have not been peer reviewed is very different than a study, being reproduced for conclusive findings on a n=30 with 2,190 patient roster that has been peer reviewed.
Let's look at a section from a different study.

> ***Main results***
>
> *Twenty-four studies met the inclusion criteria, with a total of 2882 participants with rheumatoid arthritis. Included studies Investigated physical activity interventions (n = 6 studies, 388 participants), psychosocial interventions (n = 13 studies; 1,579 participants), herbal medicine (n = 1 study, 58 participants), omega-3 fatty acid supplementation (n = 1 study, 81 participants), Mediterranean diet (n = 1 study, 51 participants), reflexology (n = 1 study, 11 participants) and the provision of Health Tracker information (n = 1 study, 714 participants).*
>
> ***Authors' conclusions***
>
> *This review provides some evidence that physical activity and psychosocial interventions provide benefit in relation to self-reported about tiredness in adults with rheumatoid*

arthritis. Currently there is insufficient evidence of the effectiveness of non-pharmacological interventions.

Looking at the aspect of this study we are most interested in, we can see that Reflexology has 1 study with 11 participants. This is far too small a population to make any firm statements about its effect on rheumatoid arthritis.

What if we each took on this as a challenge? If over a 6 month period we mimicked the 1 study that was conducted? Between our membership if we all tried to work with one or two rheumatoid arthritis case studies and were able to look at a population size of 100 or 200 individuals that made it all the way through after attrition was factored in? Now we could build some conclusive evidence to make a statement. Our involvement could be reviewed, and sourced in future systematic reviews and help build conclusive evidence for every future study on CAM.

Look for the opportunities.
When you read something like this:

The best evidence available to date does not demonstrate convincingly that reflexology is an effective treatment for any medical condition.

Rather than get angry because it does not support you, consider being the next round of study to build a case of evidence.

It is no secret the pharmaceutical field makes a good deal of money and spends a lot in research. You will find a large number of studies aimed at pharmaceutical interventions, and so there should be. As members of a free country, you not only have access to read more than just those studies, you have the ability to do your won and have them published to share as well. Not all research takes a lab and large budgets. Passionate practitioners willing to invest their time and team up with other likeminded peers play a huge role too.
The statement above came from the following research article:

Is reflexology an effective intervention? A systematic review of randomised controlled trials.

This study has a total of 18 trials with small sample sizes treating the following 13 conditions: anovulation, asthma, back pain, dementia, diabetes, cancer, foot oedema in pregnancy, headache, irritable bowel syndrome, menopause, multiple sclerosis, the postoperative state and premenstrual syndrome.
Logically, this is not “any medical condition”, but these 13. Admittedly, the trials were small, so arguably, we cannot divine statistical significance. Yet. More research is needed.

Question the statements given. What was the measure of effectively treating “ovulation? To start it? Stop it? Stop pain associated with it? Was reflexology expected to correct dementia? To lessen duration or depth of mood swings? We need to go back to these studies ourselves and better understand what was being evaluated. If the measurement used was unrealistic, or

not in the scope of Reflexology, the study is flawed. Armed with the ability to pick out flaws in research design, we can seek data elsewhere or duplicate the study and correct the flaw.

The study mentioned above was published in 2009. In 2011 we see someone reviewing the information:

> **Reflexology: an update of a systematic review of randomised clinical trials.**

What did they find?

> *Eight RCTs suggested that reflexology is effective for the following conditions: diabetes, premenstrual syndrome, cancer patients, multiple sclerosis, symptomatic idiopathic detrusor over-activity and dementia yet important caveats remain. It is concluded that the best clinical evidence does not demonstrate convincingly reflexology to be an effective treatment for any medical condition.*

How does a study become convincing? Increased population size, reliable results upon duplication and lots of it. Basically, more research still needed. Will you head the call?

It's not always a matter of thinking up a project all by yourself; you can also reproduce a previously designed study. (You can also learn from their mistakes!)
My first research project, I contacted a professor at Guelph University to ask her about her project. She was thrilled I wanted to reproduce it. So was a specialist MD who knew of the former project and a department head at Laurier University. I hadn't expected such open support and encouragement.

In 2005 the National Institutes of Health (NIH) awarded Michigan State University (MSU Kellogg Center, East Lansing, Michigan) a grant for $3.1 million to study "The Effects Of Reflexology On Women With Breast Cancer Undergoing Chemotherapy." It was the largest and the first federally funded grant in the USA for reflexology. The results of the 5-year study (2005-2010) were published in Spring 2011.

Principal Investigator, Gwen Wyatt, RN, Ph.D., is a professor for the College of Nursing, at Michigan State University. Gwen had wonderful results with reflexology to facilitate the healing of a broken tibia bone that had refused to mend using allopathic treatment options. Able to see and feel the benefits of reflexology first hand; she was led to explore the benefits of reflexology in her own field of nursing care for breast cancer. Michigan State University and Dr. Gwen Wyatt partnered with Branch Reflexology Institute for the study.

Do you have an MD or therapist who refers to you? Touch base as see if they have areas of Reflexology they'd like more information about. Even if you don't have a question in your mind, those around you might. Questions make excellent places to start a research project and build a body of evidence. You may be one, but the RRCO membership alone is hundreds. Talk about your ideas on the RRCO facebook site and get support from your peers. You could even develop an annual challenge and pick one study for everyone to reproduce. Think of what that would look like for our field in 10 years' time!

Reading critically

I once read a study that claimed to debunk Therapeutic Touch. As a practitioner myself I looked the study up. Emily Rosa is still in Wikipedia as the youngest American to be published in the prestigious Journal of American Medical Journal.
A quick read might have been concerning, but if you read the methodology, the testing was flawed. I liken it to asking someone to observe a colour and call it by name while turned to face the opposite direction then claiming the study is testing rods and cones of the eye. It was not a reasonable nor true evaluation of anything. Not surprising, the study indicated 44% accuracy "less than simply guessing" as the study concludes.
Out of interest, my husband reproduced the test that week in his college classroom, correcting the methodology flaw with his students, and had a 100% accuracy, verifying what we had assumed. The flaw in the design had impacted the results.
This can happen in any study. When reading studies, look for inconsistency, look for design flaws, and be willing to admit, when you design your own, there may be some there too.

Keeping our eyes open, even if the results are less than flattering, we can read critically, better understand what we are reading (and potential short comings) and make the most of the learning opportunity. Rather than reinvent the wheel, just inflate the tire and carry on, such as in my husband's case.

My first research project failed horribly in my placebo station. I had not allowed for the change between student therapists towards to end of my study, and the second round of interviewers were less energetic than the first, and our numbers dwindled. The lack of control I had over the duration of consistent student therapists affected my ability to honestly say whether it was the control activity or the interaction that was the root of the attrition in that group.

Being evidence based is more than just reading on google. It's evaluating, arguing and being willing to set aside your own expectations and consider what is being presented, free from outcome.

Let's look at a systematic review from a great database: PUBMED
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4003746/
I've interjected some thoughts (not italicized) as we go. Feel free to ignore them if you prefer to critically think on your own.
The search words I used were: FREE, reflexology and cancer

Abstract

1. Introduction

Cancer rates are increasing globally. According to the World Health Organization (WHO)

What do we know about this source, it's mission, who funds it, how long it's been established? Critically evaluate what you know about the "speaker" as you read.

statistics, there were about 12.7 million cancer cases in 2008, and this number is expected to increase to 21 million by 2030. Cancer is the leading cause of death worldwide, accounting for 7.6 million deaths (around 13% of all deaths) in 2008. Pain is a common and burdensome symptom associated with cancer and its treatment [1, 2].

Stop and scroll down to the 1 and 2 sources referenced. How old are they? In research studies 5yrs or newer are ideal.

Most of cancer patients suffered pain due to the cancer itself (the tumor pressed on bones, nerves, or other organs), the treatment, or the tests done to diagnose cancer. It was said that 75%–90% cancer patients experienced pain during their illness and up to 50% of cancer pain is undertreated. It was reported that one quarter of the patients had newly diagnosed malignancies, one third of the patients are undergoing treatment, and three quarters of the patients with advanced disease experienced pain [3]. For those patients with metastasis to the other places, pain is especially prevalent. And it was reported that up to 80% of the cancer patients who have bone metastasis experienced pain [3].

Pain management is important in oncologic care and essential for maximizing patient outcomes [2, 4]. Mounting evidence showed that unrelieved pain significantly comprised overall quality of life and effective pain control was associated with survival [2, 4].

There are great statements her within the last 2 sentences that I might quote in an introductory letter to a physician if hoping to develop stronger referral and communication in my community.

Health care practitioners depend heavily on opioid therapies for cancer pain. Although this therapy is very effective, it is with a lot of side effects, such as constipation, urinary retention, nausea, sedation, respiratory depression, myoclonus, delirium, sexual dysfunction, and hyperalgesia [5], so Complementary and Alternative Medicine (CAM), which is noninvasive and generally considered to be relatively free of toxicity, is used as an adjunct therapy with standard pain management techniques [6]. The earliest systematic review which included 18 trials showed that hypnosis, imagery, support groups, acupuncture, and healing touch were promising, particularly in the short term, but none can be recommended because of a paucity of rigorous trials [7].

Opportunity for further research!!!

And another review showed that approaches such as acupuncture, massage therapy, mind-body interventions, and music therapy could effectively reduce pain and enhance quality of life [6].

Now with the more and more published systematic reviews of CAM on adult cancer pain, it is necessary to use the methods of overview of systematic review to summarize the available evidence, appraise the evidence level, and give suggestions to future research and practice.

2. Methods

2.1. Inclusion and Exclusion Criteria

Only systematic reviews or meta-analyses of CAM on adult cancer pain were included. Patients were diagnosed with cancer, regardless of cancer types. The interventions were CAM or CAM in combination with conventional cancer treatments. Here, we used the definitions by the WHO: "A comprehensive term used to refer to both traditional medical systems such as traditional Chinese medicine, Indian ayurverda, Arabic unani medicine, and to various forms of indigenous medicine" [8]. The treatments include psychological and self-help therapies, physical therapies (aromatherapy, acupuncture, massage, reflexology, and shiatsu), and unconventional medicine or drugs (homeopathy, herbal medicine, Essiac, and Bach flower remedies) [7]. If there were several systematic reviews that evaluated the same interventions on adult cancer pain, we included the one that included most primary studies.

2.2. Data Source and Study Selection

We searched the Cochrane Library, PubMed, Embase, and ISI Web of Knowledge using the search term (Alternative medicine OR Homeopathy OR Acupuncture OR Reflexology OR Mind-body medicine OR Hypnosis OR Imagery OR Relaxation techniques OR Support groups OR Creative outlets OR music OR Biologic-based therapies OR Dietary supplements OR herbal OR nonherbal OR Manipulative and body-based methods OR Massage OR aromatherapy OR Magnet OR laser therapy OR Energy therapies OR Healing touch OR Reiki OR Complementary medicine OR Complementary Therapies OR Complementary Therapy OR Essiac OR traditional medicine OR shiatsu OR Ayurveda OR Phytotherapy) AND (cancers OR cancer OR neoplasm OR neoplasms OR tumor OR

tumors OR adenocarcinoma) AND (pain OR pains) AND (meta-analysis OR meta-analyses OR systematic reviews OR systematic review) as title, abstract, or keyword. If possible, the medical heading terms such as MESH and EMTREE words were used.

Searches are built to use AND, OR as inclusion/selection criteria. You can expand or narrow your searches by using these words in the search bar.

The reference lists of included systematic reviews were checked. All searches were conducted at 31 May, 2013, and updated at 31 August, 2013, and 17 February, 2014. There were not any restrictions in language, publication date, or publication type. Two authors (Yanju Bao & Xiangying Kong) independently selected studies according to the inclusion criteria, and differences were resolved by a third reviewer (Baojin Hua).

2.3. Data Collection and Analysis

We used "assessment of multiple systematic reviews" (AMSTAR) [9] to assess the methodological quality of systematic reviews, as studies showed that it has satisfactory interobserver agreement, reliability, and construct validity [10, 11].

AKA less risk of flaws to skew results

This checklist contains 11 items: "a priori" design, duplicate study selection and data extraction, comprehensive literature search, the status of publication used as an inclusion criterion, a list of studies (included and excluded), the characteristics of the included studies, assessing and documenting the scientific quality, using the scientific quality appropriately in formulating conclusions, appropriate methods to combine the findings, assessing the likelihood of publication bias, and the conflict of interest. This checklist could not give a total score for the methodological quality, so we adopted the revision version [12]: Revised Assessment of Multiple Systematic Reviews (R-AMSTAR). This R-AMSTAR did not destroy the content and construct validity of AMSTAR [12]. According to this checklist, 44 is the maximum value. However, for item 2 in R-AMSTAR, it focuses on data extracting, and it seemed to ignore study selection. As we know, efforts to enhance objectivity and avoid mistakes in study selection are important [13]. Thus, we added item 2.1 (duplicate study selection) according to item 2 in R-AMSTER. So the total score for R-AMSTER was 48. And we defined the systematic review as of high quality

(the score >36), moderate quality (the score >24), low quality (the score >12), and very low quality (the score ≦12).

Resources such as Making Sense of Research by Martha Brown Menard or anything written by Tiffany Field can be consulted for further development of research design, analysis and development.

For the evaluation of the evidence levels for the outcomes, we used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach which specifies four levels of quality: high, moderate, low, and very low quality evidence [14]. Two investigators (Liping Yang & Rui Liu) extracted data from included studies; differences were resolved by a third reviewer (Baojin Hua). The data extraction form summarized key characteristics of systematic reviews, including information on participants, interventions, outcomes, author's conclusions, and items about quality.

3. Results

3.1. Search Results

We found 1318 citations by searching medical databases (Cochrane library: 531, Pubmed: 237, Embase: 328, ISI web of knowledge: 222) and 42 citations by reference tracking. After screening titles and abstracts, we excluded duplications (236 citations), studies that were not about cancer (293 citations) or CAM (351 citations) and that were not systematic reviews (301 citations). We also excluded studies that were not about pain (75 citations) or cancer (69 citations) based on screening the full text. Finally, we included 35 papers [7,15–48] for this overview, but we only reviewed 27 papers [19–21, 23–34, 36–40, 42–48] in our paper, as some of them were overlapped.

That's a lot of leg work through reputable databases to bring into focus 27 relevant and unique papers. Another example of how one hot shot new study may or may not be all it's cracked up to be.

3.2. Characteristics of Included Systematic Reviews

One systematic review [7] was about all CAM interventions; it focused on acupuncture, music, herbal supplement/Ai-TongPing, massage, and healing touch. The other 34 systematic reviews were about psychosocial interventions [15, 16, 22, 38, 42, 44, 45], massage therapy [17, 21, 24, 33, 46], acupuncture [18, 35, 36, 41, 43], ***reflexology [23, 30, 32],***

Let’s quick look at these studies on the reference list, (23,30 and 32), save the titles, and pull them up later. Likely there will be interesting quotes and possibly methodology information for duplication should we choose.

Chinese herbal medicine [20, 40, 48], music therapy [31, 39], transcutaneous electric nerve stimulation [37], cupping [34], cannabis [27], lycopene [25], Viscum album L (European Mistletoe) [29], Reiki [28], homeopathic therapy (Traumeel) [19], creative arts therapies [47], and internal qigong [26].

3.3. Quality of Included Systematic Reviews

The total score for all systematic reviews ranges from 20 to 34 and all were of low or moderate quality. Of these systematic reviews, 23 [17, 18, 21, 22, 26–28, 30–33, 35–40, 42, 44–48] were of moderate quality and twelve [7, 15, 16, 19, 20, 23–25, 29, 34, 41, 43] were of low quality.

Six systematic reviews [7, 17, 31, 35, 37, 45] have “a priori” design, four systematic reviews [26, 31, 36, 39] conducted duplicate data extraction, six systematic reviews [17, 22, 38, 40, 43, 45] conducted duplicate study selection, 25 systematic reviews [7, 15–18, 21, 23–26, 29–35, 37, 40, 42–47] have comprehensive literature search, all systematic reviews provided a list of studies (included and excluded), 24 systematic reviews [15–17, 19–21, 24, 26–28, 30–32, 35–37, 39, 40, 42–46, 48] provided the characteristics of the included studies, and five systematic reviews [27, 30, 31, 33, 39] assessed and documented the scientific quality of the included studies. The other details of quality were presented in Table 1.

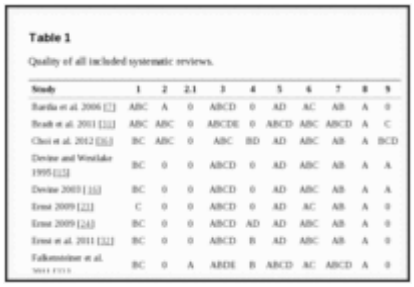

Table 1

Quality of all included systematic reviews.

Study	1	2	2.1	3	4	5	6	7	8	9
Bardia et al. 2006 [17]	ABC	A	0	ABCD	0	AD	AC	AB	A	0
Beath et al. 2011 [18]	ABC	ABC	0	ABCDE	0	ABCD	ABC	ABCD	A	C
Choi et al. 2012 [20]	BC	ABC	0	ABC	BD	AD	ABC	AB	A	BCD
Devine and Wesdaker 1995 [15]	BC	0	0	ABCD	0	AD	ABC	AB	A	A
Devine 2003 [16]	BC	0	0	ABCD	0	AD	ABC	AB	A	A
Ernst 2009 [21]	C	0	0	ABCD	0	AD	AC	AB	A	0
Ernst 2009 [24]	BC	0	0	ABCD	AD	AD	ABC	AB	A	0
Ernst et al. 2011 [32]	BC	0	0	ABCD	B	AD	ABC	AB	A	0
Falkenstörfer et al. 2001 [33]	BC	0	A	ABDE	B	ABCD	AC	ABCD	A	0

Table 1

Quality of all included systematic reviews.

3.4. Summary of Findings

Five systematic reviews [17, 21, 24, 33, 46] were about massage on cancer pain. Two systematic reviews [17, 21] used the same included studies, and two systematic reviews

[24, 33] included different studies, although they both conducted search after 2006. And the fifth [46] was a meta-analysis about breast cancer. So we reviewed four of them [21, 24, 33, 46]. Three of them [21, 24, 33] gave a conclusion that massage may have a beneficial effect on cancer pain without pooling the data. However, they included different primary studies: four randomized controlled trials (RCTs) [49–52] for systematic review by Wilkinson et al. [21], five RCTs [21, 50, 53–55] for systematic review by Ernst et al. [24], and three RCTs [51, 53, 56] for systematic review by Falkensteiner et al. [33]. The fifth systematic review [46] pooled the data and showed no benefits of massage on pain for breast cancer patients based on four different RCTs [57–60]. So based on available evidence, we could see that the conclusions for the benefits of massage on cancer pain were conflicted.

Four systematic reviews [18, 35, 36, 43] assessed the effects of acupuncture on cancer pain. The latest one [43] reviewed all available evidence of acupuncture plus drug therapy versus drug therapy on cancer pain and showed that acupuncture plus drug therapy might be better than drug therapy. Among the remaining three systematic reviews, the one by Choi et al. [36] was the most comprehensive one. This systematic review showed that acupuncture did not generate better effects on pain relief than drug therapy and sham acupuncture and that acupuncture plus drug therapy was better in managing cancer pain than drug therapy. In a word, available evidence showed that acupuncture plus drug therapy might be better than drug therapy in managing cancer pain.

How will you use this information? Do you have an Acupuncturist you refer to as a peer? Would this impact your decision to contact one if you don't?

Three systematic reviews [15, 16, 38] assessed the effects of psychosocial interventions on cancer pain and the latest [38] was the most comprehensive one. This systematic review [38] included 37 RCTs and showed that psychosocial interventions had medium-size effects on cancer pain severity and interference. Two systematic reviews [42, 45] assessed the effects of psychosocial interventions on pain for breast cancer patients. Both showed benefits on cancer pain, although they included different studies. Two systematic reviews [22, 44] assessed the effects of educational interventions on cancer pain, of them

one [44] is the more comprehensive which showed that educational interventions can result in modest benefits in the management of cancer pain. Totally, psychoeducational interventions including psychosocial and educational interventions could be helpful for managing cancer pain.

Three systematic reviews [23, 30, 32] assessed the effects of reflexology on cancer pain. Two systematic reviews [23, 32] included one crossover RCT about breast and lung cancer, and the other systematic review [30] included two N-RCTs about breast cancer. Although these three systematic reviews included few studies, they all showed that reflexology may be beneficial in reducing cancer pain.

How do we go from “may” to does? More research.

Three systematic reviews evaluated the effects of Chinese herbal medicine on cancer pain [20, 40, 48]. Systematic review by Xu et al. [20] showed that Chinese herbal medicine may be useful for managing cancer pain. The meta-analysis by Wang et al. [48] showed that Chinese herbal medicine plus conventional treatment increased the pain-relief rate as compared with the conventional treatment for pain secondary to bone metastases, and the meta-analysis by Bao et al. [40] showed that Chinese medicine, compound kushen injection, was associated with improving pain relief for bone cancer pain. Totally, we could see that Chinese herbal medicine may be beneficial in managing cancer pain.

Two systematic reviews [31, 39] evaluated the effects of music interventions on cancer pain. However, their included studies were different, as they were conducted at different times and/or by authors in different countries. These two systematic reviews showed that music interventions were associated with a moderate pain-reducing effect for cancer patients.

For other CAM interventions, lycopene [25], qigong [26], cupping [34], cannabis [27], Reiki [28], homeopathic therapy (Traumeel) [19], transcutaneous electric nerve stimulation (TENS) [37], creative arts therapies [47], and Viscum album L [29], there was only one systematic review for each. Studies showed that lycopene, qigong, cupping, cannabis, homeopathy (Traumeel), creative arts therapies, and Reiki might have beneficial effects on cancer pain. For TENS and Viscum album L, evidence was less consistently.

3.5. Evidence Level

Among the 27 systematic reviews we summarized, 18 systematic reviews [19–21, 23, 25, 27, 28, 31–34, 36,37, 39, 40, 45, 46, 48] have small sample size, there were high heterogeneity in eight systematic reviews [19,29, 31, 36, 39, 43, 46, 47], the risks of bias of 22 systematic reviews [19–21, 23–25, 27–29, 32, 34, 36–38,40, 42–48] were high, and two systematic reviews [26, 30] included observational studies. So based on GRADE approach, the evidence levels for music, reflexology, lycopene, qigong, cupping, cannabis, Reiki, TENS, Chinese herbal medicine, homeopathy (Traumeel), creative arts therapies, and Viscum album L were low. For acupuncture, evidence was low for acupuncture or acupuncture + drug therapy (versus drug therapy) and very low for acupuncture (versus sham acupuncture). For massage therapy and psychoeducational interventions (psychosocial and educational interventions), the number of included studies was different, so the evidence level was low or moderate.

4. Discussion

4.1. Summary of Finding

Based on available evidence, we could find that psychoeducational interventions, music interventions, acupuncture plus drug therapy, Chinese herbal medicine plus cancer therapy, compound kushen injection, reflexology, lycopene, TENS, qigong, cupping, cannabis, Reiki, homeopathy (Traumeel), and creative arts therapies might have beneficial effects on adult cancer pain. No benefits were found for acupuncture (versus drug therapy or shame acupuncture), and the results were inconsistent among studies for massage therapy, transcutaneous electric nerve stimulation (TENS), and Viscum album L plus cancer treatment. The methodological quality for primary studies was not very good and the evidence levels for these interventions were low or moderate, so firm conclusions could not be drawn. Based on all evidence we collected, we could not recommend any CAM interventions for adult cancer pain because of small sample size, high heterogeneity across studies, and high risk of bias for primary studies.

It was reported that the use of CAM among cancer patients is widespread and appears to be increasing [8].

That’s another usable quote

Surveys on the use of CAM among cancer patients have been reported as high as 64% and as low as 7% [61]. For example, a survey on the use of CAM among patients with haematological cancers in 14 European countries showed that 36% of cancer patients in Europe have used one or more forms of CAM modalities [62]. Similar studies in New Zealand and Canada showed 42% and 43% prevalence rate of CAM use among cancer patients [63, 64].

Cancer patients were hoping to better control cancer and cancer-related pain, so they turned to CAM. Ernst [65] grouped the reasons given by patients for their use of CAM into push factors (negative) which pushes patients away from conventional medicine and pull factors (positive) which relates to the positive aspects of CAM. Study also showed that CAM might give cancer patients strength to go through the conventional therapies, relieve their symptoms, improve their quality of life [66, 67], and further increase the body's ability to fight off the disease [62].

This is great to understand exactly what is needed in order to meet the needs/expectations of these patient groups.

Although more and more cancer patients turned to CAM to cure their disease, the evidence levels for the benefits of CAM on cancer pain were not satisfied. We could see from Table 2 that the evidence levels for all interventions were low or moderate. For most interventions, they were of low evidence level. Among these interventions, acupuncture plus drug therapy, Chinese herbal medicine, creative arts therapies, cannabis, cupping, lycopene, Reiki, qigong, music interventions, homeopathy (Traumeel), and reflexology might be beneficial in reducing cancer pain. Only two interventions (psychosocial intervention and massage therapy) from five systematic reviews were of moderate evidence level. However, definitive conclusions were not achieved for most of them due to the methodological problems and/or small sample size.

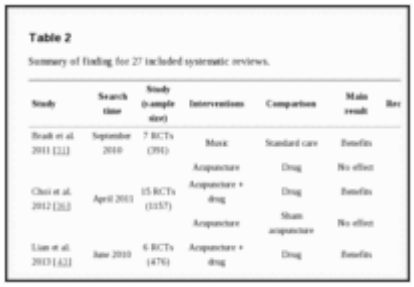

Table 2

Summary of finding for 27 included systematic reviews.

Study	Search time	Study (sample size)	Interventions	Comparison	Main result	Ref
Boath et al. 2011 [21]	September 2010	7 RCTs (391)	Music	Standard care	Benefits	
			Acupuncture	Drug	No effect	
Choi et al. 2012 [26]	April 2011	15 RCTs (1157)	Acupuncture + drug	Drug	Benefits	
			Acupuncture	Sham acupuncture	No effect	
Lian et al. 2013 [42]	June 2010	6 RCTs (476)	Acupuncture + drug	Drug	Benefits	

Table 2

Summary of finding for 27 included systematic reviews.

Where does the unsatisfied evidence level come from? According to 27 systematic reviews we summarized, small sample size, high heterogeneity across studies, and high risk of bias for primary studies were the reasons. Trials of complementary therapies often have relevant methodological weaknesses [68]. According to the systematic review by Garcia et al. [41], 33 of 41 RCTs about acupuncture for symptom management in cancer care were of high risk of bias. The earliest systematic review [7] of CAM in relieving cancer pain also found that the included RCTs were of high risk of bias. Studies have also found that insufficient sample size was common in CAM studies [69, 70]. For heterogeneity, that might be due to different administrative ways of CAM. So in the future, when designing the RCTs that compared CAM with placebo or other interventions, a rational sample size calculation should be well done. Meanwhile, the key methodological aspects, such as methods of randomization, concealed allocation, and blinding, should be well conducted and reported.

It makes me wonder what the results would be in a study that had 4 groups. One treatment with a tool/robotic device, one with a therapist's touch, one self-treatment and one group no treatment (placebo). The three groups experiencing treatment would have the same schedule of treatment, and same duration. A survey of pain levels and limitations would need to be done pre and post the caser studies. If possible quantitative measures like using a tape measure to chart swelling in legs, or range of motion assessment, or a pain scale to provide as concrete data as possible would be ideal. Listing limitations in daily living would be another type of charting to compare before and after. What are ***you*** thinking?

4.2. Strength and Limitations

Our overview was the first one which systematically reviewed available systematic reviews of CAM on adult cancer pain. We searched medical databases and hand-searched reference lists and used GRADE to evaluate the evidence levels for each kind of CAM. However, our systematic overview had its own limitations. First, we only included systematic reviews and this means that we did not include primary studies that evaluated CAM for adult cancer pain. For reflexology, the systematic reviews in our overview showed that reflexology might be beneficial on adult cancer pain, but a recent study showed no differences among reflexology, lay foot manipulation, and conventional care [71]. For yoga, there was not a systematic review that evaluated its effect on cancer pain. A recent RCT [72] which compared yoga with wait-list control showed that the yoga group reduced daily joint pain for breast cancer patients. Second, the critical problem

for these primary RCTs of CAM on adult cancer pain was of low quality and of small sample size. For example, all included RCTs in the systematic review by Choi et al. [36] were associated with high risk of bias. Meanwhile, few studies were included in systematic reviews. For example, only one crossover RCT and two N-RCTs were about reflexology, two RCTs were about Reiki, and one RCT was about cupping.

4.3. Implications for Future Research and Practice

Due to high risk of bias for primary studies, the evidence levels for each CAM were low or moderate. So in the future, in order to prescribe CAM, the health care professionals should be more careful.

When designing research, let's make sure we are pooling information objectively, without bias and en-mass.

Based on available evidence, we could not recommend any CAM interventions for cancer pain due to small sample size, high heterogeneity across studies, and high risk of bias for primary studies.

The methodological quality for primary studies was low and their sample size was small, so in the future large and well-designed RCTs should be conducted to confirm the conclusions of available systematic reviews.

5. Conclusions

Based on available evidence, psychoeducational interventions, music interventions, acupuncture plus drug therapy, Chinese herbal medicine plus cancer therapy, compound kushen injection, reflexology, lycopene, TENS, qigong, cupping, cannabis, Reiki, homeopathy (Traumeel), and creative arts therapies might have beneficial effects on cancer pain. No benefits were found for acupuncture (versus drug therapy or shame acupuncture), and the results were inconsistent among studies for massage therapy, transcutaneous electric nerve stimulation (TENS), and Viscum album *L plus cancer treatment. The methodological quality for primary studies was not high and the evidence levels for these interventions were low or moderate, so firm conclusions could not be drawn. Based on all evidence we collected, we could not recommend any CAM interventions for adult cancer pain because of small sample size, high heterogeneity across studies, and high risk of bias for primary studies.*

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Conflict of Interests

The authors declare that they have no conflict of interests, as the funder did not play any role in study design or conduct.

An example of a conflict of interest would be if the primary investigator was on the payroll of a company who would either benefit or be hurt by the research findings.

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Hopefully you read that and said “wow” there’s a lot of room for me to get involved because there is a whole lot more research neeed in order to provide the Western Medical world with the type of data they are accustomed to.

As an ancient indigenous healing art, we too can grow and speak in the modern medical arena. We just need to decide we want to and jump in.

CEU Questions

Please answer the following and keep your responses in an electronic file for submission at the end of your CE cycle.

1) What is one (or more) questions regarding reflexology that you have had, that you have not been able to find a solution to?

2) Have you brought it to the RRCO facebook group? Have you sound boarded with peers in this or other modalities? Have you tried a reflexology text book? Is your question of a more broad scope? Perhaps asking to borrow and anatomy text or pathology text form a peer is in order. Have you asked your former school? Instructors are great sources of further knowledge. If they don't know, they can also open a new branch of connections to you for continued seeking. Please describe your thoughts in 250 words or more.

3) What are 2 databases of research available on line?

4) When reading a research paper it is ideal for it to be which of the following?
   a) Peer reviewed and well established by being at least 10 years old
   b) An opinion based story
   c) Peer reviewed and within the last 5 years
   d) Costly, they are always better

5) What is the difference between quantitative and qualitative recording measures in research?

6) What are some of the challenges CAM faces, based on what you've read?

7) How could you play a role in aiding Reflexology move forward in a western medical model of communication?

8) Does having an ancient history mean we do not or should not participate in research? Why or why not? Please describe in 250 words or more.

9) After reading this article, are you more or less likely to search and read research? Please explain in 250 words or more.

Thank you for joining me in this CEU experience! All the best in your learning adventures!

Robynne Kingswood, RRPr, RMT
Faculty, OVCMT