Oncology Care and Acupuncture: A Systematic Review of Acupuncture Treatment for Hot Flashes and Xerostomia

A Capstone Project Submitted by
Tyler N Andres, MAcOM

for completion of the requirements for the degree of
Doctor of Acupuncture and Oriental Medicine

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Acknowledgments

My journey to study acupuncture and Chinese Medicine occurred because of my mother’s experience with acupuncture through her oncology care. I want to especially thank her and my father, and my entire family for their enduring support through this journey. For her support and patience, I especially thank my wife, Andryce.

I also want to give a special thanks to Dr. Beth Burch for her guidance and clarity through this project. Without her help and support, and her constant source of positivity, this research would have been impossible to complete.
1) Introduction

In the course of humanity there are multiple periods in history where plague, disease and illness devastated populations. These illnesses were unstoppable by the care given from physicians at the time. In the modern Western world we have achieved medical miracles. Many of the plagues of the past no longer haunt our populations because of the efficiency of vaccines, emergency care, and modern technology. We can keep people tethered to life, even in the most unlikely and implausible situations.

However, we continue to have plagues amidst our populations. These plagues commonly present themselves as simmering and occult illnesses. These are not the virulent or contagious plagues of the past, but they still reside amongst us, are difficult to control, and take lives at an ever increasing rate. One of these modern plagues is cancer, and cancer in all its forms and complexity, continues to belie the odds of the modern medical world.

In the modern care of cancer there is an ever growing array of treatment options. Medications, diagnostics, and surgical procedures are extending lives and diagnosing cancer earlier than ever before. Survivorship rates are increasing with some types of cancer, but prevalence of the disease is increasing across many fronts. The exact causes of cancer are still being explored, and understanding genetic and environmental links to the disease are still under deep investigation.

The prevalence of cancer worldwide is growing. In 2008 it is estimated that 28.8 million individuals were diagnosed with cancer in the previous 5 years, with 12.7 million of those cases being new cases of cancer. Mortality resulting from cancer was around 7.6 million.¹ In the
United States the most recent data from the Center for Disease Control shows that in 2010 the top five diagnosed cancers were prostate, breast cancer in women, lung cancer, colon cancer, and uterine cancer. Just these five cancers together affect nearly 400 of every 100,000 individuals living in the US.\(^2\) When all cancer types are taken together, including cancers beyond the top five diagnosed, there are around 461 of every 100,000 individuals affected in the US, with over 4.5 million new diagnoses per year.\(^3\)

In many cases the very treatments for cancer lead to a constellation of side effects and problems that can greatly affect the quality of life for the individual undergoing treatment. Common side effects from medications and surgical interventions include nausea and vomiting, fatigue, pain and physical malaise, hot flashes, anxiety and depression.\(^4\)\(^-\)\(^9\) Included in the regimen of treatment options for these debilitating side effects, patients are seeking out care from Complementary and Alternative Medicine apart from the traditional Western treatment options. The exact number of patients who seek out alternatives is not completely well determined due to factors such as hesitation in self-reporting, or lack of follow up with patients once their Western oncological care is complete. Some research shows that as much as 54\% of oncology patients seeking this type of care, other estimates are much lower, around 10\%.\(^10\) This dramatic spread in estimates around CAM use shows variability in self-reported activity and difficulty in estimating the exact amount of CAM therapies being utilized by this population.

2) Acupuncture in Oncology Care

The role of acupuncture in oncology care is being developed and better understood through research, case studies, and observation. In 1997 the National Institute of Health held a
Consensus Conference on acupuncture. The conference looked at research available for many different conditions in relation to acupuncture care. The conclusions they reached were limited and very specifically targeted to conditions where acupuncture was shown effective. In relation to oncology care and patient care, they concluded that, based on the existing evidence and clinical trials at that time, it noted a beneficial role for acupuncture in the areas of chemotherapy-induced nausea/vomiting.11

This limited ruling by the NIH was a step forward at that time in relation to the acupuncture field. However, those results were based on data present in the late 90’s. There is a significant amount of additional research that has been produced in relation to acupuncture and oncology outside of the category of chemotherapy-induced nausea and vomiting. Because the NIH has yet to update their consensus statement with current research outcomes, it has had the effect of narrowing the treatment options available for oncology patients. Specifically, insurance companies will limit reimbursement based on these recommendations and not cover care for any additional symptoms occurring with oncology care. The goal of this review is to shine light on whether or not it is appropriate, in relation to current research, to broaden the NIH Consensus Statement to possibly recommend acupuncture as adjunctive treatment for the care of oncology patients.

There are a broad number of secondary conditions that occur during oncology care. Secondary conditions result, most typically, as side effects of oncology drugs such as chemotherapy. Some conditions may also result from the use of radiation therapy to destroy cancer cells, or from surgery to remove tumors and metastasis. Though the list of secondary conditions is extensive, the most commonly experienced include: pain, joint pain and/or
disfiguration, hot flashes, fatigue, depression and/or anxiety, insomnia, lymphedema, emesis and nausea.¹²-¹⁴

Though it may or may not be appropriate to recommend acupuncture as adjunctive care for all of these conditions, there is a growing body of evidence that acupuncture may be a cost-effective and appropriate alternative to conventional treatments such as drugs. Some conditions that are receiving the most research include hot flashes, general quality of life measures in oncology patients, and physical symptoms in oncology such as nausea and vomiting and pain.¹⁵

Though some of these conditions were considered for this systematic review, limitations were placed on the scope of the review. There were a significant number of articles detailing acupuncture for oncology related pain.⁴⁰-⁴⁷ However, the use of acupuncture for pain is well studied in many contexts, with the body of evidence showing significant potential for acupuncture in relation to this condition. In addition, dating back to the NIH statement from 2008, there is continued research into the use of acupuncture for oncology related nausea and vomiting.⁴⁸-⁵⁵ However, the use of acupuncture for this condition is well-established, and the benefit of doing a systematic review on this condition is limited due to the presence of already established research and acceptance of the topic in the field. In contrast, the understanding of acupuncture for hot flashes in oncology, as well as radiation-induced xerostomia, is not well understood or established within the research community. There is benefit to be found through the exploration of these two conditions, and the role that acupuncture may possibly have in the care of these patient populations.
3) Systematic Review - Inclusion and Exclusion Criteria

The inclusion and exclusion criteria for this systematic review were selected to include the most recent evidence for research in the areas of acupuncture and oncology care for hot flashes and xerostomia. Articles were selected from the last 10 years of published research in peer-reviewed journals. Randomized controlled trials, as well as observational studies were included in the review. The articles were limited to those published in complete text form, and written in English. Articles in other languages were excluded. Though the publication of pilot studies, or “feasibility” studies may demonstrate a possible trend in care for patients, those articles were excluded from this review in an attempt to gain the best grasp possible of robust evidence for outcome measures. Systematic reviews published in the last 10 years, and covering the specific topics were included in a narrative review form. This was done to better understand what other larger reviews’ conclusions are, when available.

The initial search for possible articles was done on major peer-review indexes including: Pubmed, Ebsco Host, and Google Scholar. Initial searches were performed for Acupuncture and Oncology care with over 1247 article matches meeting initial review. An initial review of title and abstract eliminated articles that were pilot studies, or articles that were not pertinent to the topics of hot flashes, fatigue and xerostomia. There were 72 articles meeting basic inclusion criteria based on title and abstract review. Those 72 were located in full text form and reviewed at length. In the main categories of hot flashes there were 12 articles reviewed, 10 of which were either randomized control trials or observational studies. There were 2 articles which were included which were systematic reviews of acupuncture and hot flashes. In the category of
xerostomia there were 6 total articles, 4 of which were trials. There were 2 systematic reviews of xerostomia.

4) Description of Review Methodology - CONSORT and STRICTA

In the research and publication environment there are international standards that exist for the consistency and quality of published, peer-edited works. CONSORT (Consolidated Standards of Reporting Trials) is the most accepted and utilized standard amidst the publications of randomized and controlled trials (RCT). The CONSORT 2010 Statement includes in-depth analysis of all components of a research article starting from the title and abstract of the article, all the way through to the discussion section, registration and funding. There are detailed elements in relation to the methods and results sections, looking closely at randomization, blinding methods, statistics, recruitment and participation. For the purpose of this systematic review a modified version of CONSORT was used to analyze the selected articles. The evaluation that was used included a review of: Abstract/Title, Introduction, Methods (trial design, participants, outcome, and sample size), Randomization (type of randomization, allocation, concealment, implementation, blinding), Results (participant completion/implementation rates, baseline data, analysis, outcomes), Outcome Measurements, Time Frame of Outcome Measures, Discussion (limitations, generalizability, interpretation). A full description and explanation of the CONSORT statement is available online.16

Though the CONSORT statement is useful for any research article involving a randomized controlled trial, due to the specificity and details of an acupuncture intervention, and
how those details differ widely from other interventions such as a drug trial, another standardized evaluation specified for acupuncture was consolidated. This is referred to as STRICTA (Standards for Reporting Interventions in Controlled Trials of Acupuncture). STRICTA guidelines include the detailed analysis of Acupuncture Rationale (style of acupuncture, reasoning for the treatment, variation of the treatment), Details of Needling (number of insertions, names of points, depth of insertion, stimulation of needles, needle retention and needle type), Treatment Regimen (number of treatments, frequency of treatments), Other Components of Treatment (details of adjunctive interventions, setting of the treatment), Practitioner Background (description of participating acupuncturists), and Control or Comparators Interventions (rationale for the control or comparator in relation to the research question, description of the control or comparator - sham acupuncture). In this systematic review STRICTA was used in its entirety to review and compare the wide variety of acupuncture protocols and interventions implemented for hot flashes and xerostomia.

5) Review of Articles on Acupuncture for Hot Flashes in Oncology Care

There were a total of 10 articles that met the inclusion criteria for this systematic review in the subcategory of Hot Flashes in Oncology Care. There were two systematic reviews completed in the last 10 years on the subject of Acupuncture and treatment of hot flashes in oncology. Though these two systematic reviews could not be analyzed according to the STRICTA and CONSORT methodology, they were included in this systematic review in narrative form to further bolster understanding of the subject, as well as an additional
comparison of RCT studies which may have been included in these systematic reviews which were not included in this review due to date of publication, or possible status as a pilot study.

When comparing between the different STRICTA criteria within the studies there are interesting trends that can be noted. When reviewing the studies in relation to rationale of the acupuncture used in the study, there is a noted lack of any description of the style of acupuncture used. In the studies from Hervik (2009) and De Valois (2010) there is a specification of the style of acupuncture being performed. In the Hervik study the authors specify a “TCM” style, meaning Traditional Chinese Medicine approach. It could possibly be assumed that a majority of the studies, even when not specified, likely employed some type of Traditional Chinese Medicine (TCM) style due to the prevailing nature of text books and training in the West. The De Valois study specified both a 5 Element style of acupuncture as well as a TCM approach to some of the treatment, and was unique in that it both specified and utilized two different styles of acupuncture.

About 50% of the studies provided some reasoning and a reference for the acupuncture points they used in the study. This is an area where the studies fell very short in quality of reporting and study design. The fact that 5 of the studies did not even provide reason for acupuncture point choice, nearly invalidates those studies on that measure alone. If points are selected at random, or there is no reference for the selection it is no different than studying two medications for a disease and picking the medications at random from hundreds of options. There were three of the studies that gave a limited reference to their reasoning for the acupuncture performed. These texts may have stated that the same protocol was used in other studies, but they did not give a rationale based on acupuncture principles. In fact, of the ten
studies reviewed there were only two that gave a rationale for the choice of acupuncture points that was framed in an acupuncture or Chinese Medicine perspective.

Finally, a majority of the studies did not have any variation in the treatment provided for the patients. There were two studies that allowed point selection based on pattern differentiation and variation of treatment within certain parameters based on what was most appropriate for the patient’s condition. Six of the studies did not allow for any variation within the treatment protocol, and two did not have any reference to this aspect of the treatment setting.

Below is a summary of the 10 articles using the STRICTA Criteria for Acupuncture Treatment Given.

<table>
<thead>
<tr>
<th>Rationale for Acupuncture Treatment - Acupuncture for Hot Flashes in Oncology</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Acupuncture rationale</td>
</tr>
<tr>
<td>--------------------------</td>
</tr>
<tr>
<td>Liljegren A, 2012.</td>
</tr>
<tr>
<td>Beer TM, 2010.</td>
</tr>
<tr>
<td>Bokmand S, 2012.</td>
</tr>
<tr>
<td>Filshie J, 2005.</td>
</tr>
<tr>
<td>Frisk J, 2008.</td>
</tr>
<tr>
<td>Hervik J, 2009.</td>
</tr>
<tr>
<td>De Valois BA, 2010.</td>
</tr>
<tr>
<td>Walker EM, 2010.</td>
</tr>
<tr>
<td>Frisk J, 2009.</td>
</tr>
<tr>
<td>Deng G, 2007.</td>
</tr>
</tbody>
</table>
The needling details evaluated between the different studies for oncology patients and acupuncture for the treatment of hot flashes is shown in the second table below. Most of the studies met minimum criteria, however, it must be understood that a study lacking data in this area is a serious problem. These aspects of the treatment are important because acupuncture is a very specific intervention. In order to replicate an acupuncture study, essential details of types and sizes of needles, needle insertion depth, time needles are left in, are all important.

The actual number of needles used in treatment, specified as number of needle insertions, was given in 8 of the 10 studies. One study failed to state unilateral versus bilateral placement of the needles (Walker, 2010), and one failed to mention even the most basic of information around what points were being used or how many points were being used in the treatment group for the study (Frisk 2008). Nearly all of the studies did detail the name or actual location of the points being used, with the exception again of the article by Frisk from 2008. Four of the articles failed to describe the depth of needling used for the points selected. In the Bokmand study published in 2012, the depth for the sham treatment is given but no details are included regarding the group receiving true acupuncture. Depth of needling is, potentially, a very important aspect of acupuncture and understanding the physiology of how acupuncture works. It could be that different depths and related tissue structures may be involved in the mechanisms behind the results found through acupuncture treatment.

Like needle depth, manipulation and stimulation of needles after insertion may play a role in the physiology of the acupuncture intervention itself. Traditionally acupuncture is taught in relation to seeking out a sensation at the needling area, sometimes referred to as “de qi”
sensation. This sensation is described in many different ways, but is typically not a painful sensation. Six of the articles described the response that was sought at the needling locations, and seven of the article specified the type of intensity of needle stimulation used to obtain the response. In some cases that was through the use of electroacupuncture devices to deliver small amounts of current to the needles once they were placed.

Finally, four of the ten studies failed to describe the type of needle used. This is another mark against the quality of the reporting of the studies per STRICTA. Needles themselves come in different diameters and sizes. Knowing what type of needle was used, including the length and diameter, is important for the replication of the study in future research.

<table>
<thead>
<tr>
<th>Needling Details - Acupuncture for Hot Flashes in Oncology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2. Details of needling</strong></td>
</tr>
<tr>
<td>2a) Number of needle insertions</td>
</tr>
<tr>
<td>2b) Names/Location of points used</td>
</tr>
<tr>
<td>2c) Depth of insertion</td>
</tr>
<tr>
<td>2d) Response sought</td>
</tr>
<tr>
<td>2e) Needle stimulation</td>
</tr>
<tr>
<td>2f) Needle retention time</td>
</tr>
<tr>
<td>2g) Needle type</td>
</tr>
<tr>
<td>Liljegren A, 2012.</td>
</tr>
<tr>
<td>Beer TM, 2010.</td>
</tr>
<tr>
<td>Bokmand S, 2012.</td>
</tr>
<tr>
<td>Filshie J, 2005.</td>
</tr>
<tr>
<td>Frisk J, 2008.</td>
</tr>
<tr>
<td>Hervik J, 2009.</td>
</tr>
<tr>
<td>De Valois BA, 2010.</td>
</tr>
<tr>
<td>Walker EM, 2010.</td>
</tr>
</tbody>
</table>
The details of the treatment itself were given in all of the studies except for two: Filshie 2005 and De Valois 2010. The article by Filshie et al does not give the number treatments, nor does it specify the frequency of treatments being administered. This is a big limitation of the study report, as it means the study couldn’t easily be replicated in the future. Though the points and needles used are specified, without knowing treatment frequency or the total number of treatments given to the patient it is would be difficult to replicate what the authors have done to get the results they describe.

Most of the studies refer to points in the form most utilized by the acupuncture profession itself, or in standard texts utilized by practitioners. The nomenclature involves two letters referring to one of 14 standard “channel” lines on the body, such as BL for Bladder Channel, or ST for Stomach Channel. A number follows the letters given to describe a particular location along the channel. ST36 refers to the 36th point along the Stomach Channel, and has a standardized location in acupuncture texts.

The De Valois study from 2010 does not give treatment frequency, nor does it describe how long the treatment lasted when it was administered. All other studies gave detailed
descriptions regarding the amount of time the patients were on the table with acupuncture needles, as well as the number of treatments in the time frame. The table below describes the treatment regimen in the last column. There is a great variation between the different studies, with some treatments involving 2 treatments a week over 5 weeks, others with a variation where initial weeks of treatment were given at 2 treatments a week, and then later phased down to 1 treatment a week. The total number of treatments given in each study varies as well, from 5 or 8 total treatments, to more than 16.

<table>
<thead>
<tr>
<th>3. Treatment regimen</th>
<th>3a) Number of treatment sessions</th>
<th>3b) Frequency and duration of treatment sessions</th>
<th>Description of Treatment Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liljegren A, 2012.</td>
<td>YES</td>
<td>YES</td>
<td>2x/week for 5 weeks, 20 min total treatment time</td>
</tr>
<tr>
<td>Beer TM, 2010.</td>
<td>YES</td>
<td>YES</td>
<td>2x/week for 4 weeks, then 1/week for 6 weeks</td>
</tr>
<tr>
<td>Bokmand S, 2012.</td>
<td>YES</td>
<td>YES</td>
<td>15-20 treatment time; One treatment per week for five weeks</td>
</tr>
<tr>
<td>Filshie J, 2005.</td>
<td>NO</td>
<td>NO</td>
<td>Some patients had dermal tacks, so frequency could vary from weekly self-treatments as well as hospital visits ranging 2/week or 1, 3, or 4 per month - standardization not set</td>
</tr>
<tr>
<td>Frisk J, 2008.</td>
<td>YES</td>
<td>YES</td>
<td>2x/week for 2 weeks, then 1x/week for 10 weeks</td>
</tr>
<tr>
<td>Hervik J, 2009.</td>
<td>YES</td>
<td>YES</td>
<td>2x/wk for 5 wks, then 1x/week for 5 weeks</td>
</tr>
</tbody>
</table>
The qualifications of the treating acupuncturist(s) was only given in 3 out of 10 studies. The most common description was to state that they were “physiotherapists,” with years of experience included. The study by Deng from 2007 does state that all of the acupuncturists had at least 3 years of experience, and were licensed acupuncturists (versus other types of medical professionals). Many of the studies completely omit any reference to the acupuncturist involved in the study, and so it is impossible to know if the treatments provided were given by qualified professionals or not. It is possible that having treatments done by a practitioner not trained in the protocols and standardization of point location and needle stimulation would produce different results than treatments done by a well educated and experienced practitioner.

<table>
<thead>
<tr>
<th>Treatment Regimen and Practitioner Details - Acupuncture for Hot Flashes in Oncology</th>
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<tbody>
<tr>
<td>3. Treatment regimen</td>
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<tr>
<td>3a) Number of treatment sessions</td>
</tr>
<tr>
<td>3b) Frequency and duration of treatment sessions</td>
</tr>
<tr>
<td>Description of Treatment Regimen</td>
</tr>
<tr>
<td>De Valois BA, 2010.</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>NO</td>
</tr>
<tr>
<td>8 treatments total, no frequency is specified</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>2x/week for 4 weeks, then 1x/week for 8 weeks</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>2 per week for 2 weeks, then 1 per week for 10 weeks</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>2x/week for 4 weeks</td>
</tr>
</tbody>
</table>

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The most common description was to state that they were “physiotherapists,” with years of experience included. The study by Deng from 2007 does state that all of the acupuncturists had at least 3 years of experience, and were licensed acupuncturists (versus other types of medical professionals). Many of the studies completely omit any reference to the acupuncturist involved in the study, and so it is impossible to know if the treatments provided were given by qualified professionals or not. It is possible that having treatments done by a practitioner not trained in the protocols and standardization of point location and needle stimulation would produce different results than treatments done by a well educated and experienced practitioner.
There needs to be a greater effort by researchers to include qualified professionals, as well as to state who those professionals are when they are involved in research. This problem is highlighted by this small sample of research for hot flashes. If, for comparison’s sake only, we were to compare this problem in the research to other areas of study, it would be similar to doing a study on eye surgery without specifying who is doing the eye surgery, or what qualifications they have to do eye surgery. This presents itself as a significant limitation in the research being done, and hinders a neutral evaluation of the outcomes because of the potential for unqualified practitioners performing subpar or inappropriate acupuncture for the participants in the study.

Most studies failed to describe the treatment in regards to any additional interventions given. Chinese medicine is prescribed not only through the use of acupuncture, but includes dietary recommendations, herbal products, and exercise or lifestyle recommendations. Only two of the studies utilized other aspects of the Chinese medical intervention. Half of the studies

<table>
<thead>
<tr>
<th>Treatment Regimen and Practitioner Details - Acupuncture for Hot Flashes in Oncology</th>
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<tbody>
<tr>
<td><strong>5. Practitioner background</strong></td>
</tr>
<tr>
<td>Beer TM, 2010.</td>
</tr>
<tr>
<td>Bokmand S, 2012.</td>
</tr>
<tr>
<td>Filshie J, 2005.</td>
</tr>
<tr>
<td>Frisk J, 2008.</td>
</tr>
<tr>
<td>Hervik J, 2009.</td>
</tr>
<tr>
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</tr>
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<td>Walker EM, 2010.</td>
</tr>
<tr>
<td>Frisk J, 2009.</td>
</tr>
<tr>
<td>Deng G, 2007.</td>
</tr>
</tbody>
</table>
detailed the treatment environment, including a description of the treatment location and any communication given to the patient regarding the purpose of acupuncture.

<table>
<thead>
<tr>
<th>Other Treatment Components - Acupuncture for Hot Flashes in Oncology</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>4. Other components of treatment</strong></td>
</tr>
<tr>
<td>Liljegren A, 2012.</td>
</tr>
<tr>
<td>Beer TM, 2010.</td>
</tr>
<tr>
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<td>Deng G, 2007.</td>
</tr>
</tbody>
</table>

Some of the studies reviewed used a control or comparator in relation to acupuncture. This review included several observational studies (Frisk 2008, Beer 2010, Filshie 2005, De Valois 2010). The control in the studies is extremely variable, with some using a sham device such as the Park Sham device or the Asiamed sham device attempting to mimic or reproduce the sensation of acupuncture without actual deep needle placement, or other controls/comparators such as Venlafaxine, which is an SSRI typically used for the treatment of hot flashes.
### Control Description - Acupuncture for Hot Flashes in Oncology

<table>
<thead>
<tr>
<th>6. Control or comparator interventions</th>
<th>6a) Rationale for the control or comparator in the context of the research question</th>
<th>6b) Precise description of the control or comparator/sham device</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liljegren A, 2012.</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Park sham Needles from Dongbang used 1 cm away from the actual acupuncture points used, needle placed but no penetration to the skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beer TM, 2010.</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>No control given</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bokmand S, 2012.</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Sham points near real points, does not describe exact location</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Filshie J, 2005.</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>No control given</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frisk J, 2008.</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>Compares Hormone Therapy to Electro-acupuncture, observational study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hervik J, 2009.</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>Sham was used via same needles, 2-3 mm insertion at 8 points 5-15 cm proximal to the upper border of the patella</td>
<td></td>
<td></td>
</tr>
<tr>
<td>De Valois BA, 2010.</td>
<td>NO</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>No Control used</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walker EM, 2010.</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>The comparator/control treatment is Venlafaxine. Venlafaxine is an SSRI and is used frequently for the “pharmacologic therapy of choice” for women experiencing hot flashes as a result of breast cancer care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frisk J, 2009.</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td></td>
<td>The comparator in this study is acupuncture with electro-stimulation versus acupuncture alone</td>
<td></td>
<td></td>
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<td>Deng G, 2007.</td>
<td>YES</td>
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<td></td>
<td>The sham needle was created by Asiamed in Germany, superficial penetration of the skin</td>
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Between the various studies, there is a variety of outcome measurements that were used in relation to hot flashes. The most common is a general measurement of hot flash...
frequency. Hot flash frequency/intensity is measured a number of different ways, from self-reported data, or more standardized measurements such as the Kupperman Index (KI).

The study by Frisk from 2009 created a standardized measurement based on reported data from patients to create a “hot flash distress” measurement. There were several studies which attempted a scientific measurement in relation to hot flash frequency, including estradiol measurements, Calcitonin gene-reactive peptide (CGRP) levels, sex hormone levels, or Urinary 5-HIAA measurements. Though the exact mechanism by which hot flashes occur is not completely understood, these different measurements are thought to possibly lead to a better understanding of the pathophysiological processes leading to hot flashes. None of the tests demonstrated significant changes in these hormone levels with the use of acupuncture.

The studies vary wildly when compared regarding the time frame under which the outcomes are measured. Most studies included a baseline measurement of the outcome the researchers are looking at.

<table>
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<tr>
<th>Outcome Measurements and Time Frame of Outcomes</th>
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<tr>
<td><strong>Outcome Measurement</strong></td>
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<td><strong>Time Frame of Outcome Measurement</strong></td>
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<td><strong>Outcome Measurement</strong></td>
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<td>Liljegren A, 2012. 1) Self Reported frequency and intensity of vasomotor symptoms 2) circulating levels of estradiol, progesterone, testosterone, prolactin, Follicle stimulating hormone (FSH) and Luteinising hormone (LH) and Sex hormone binding globulin (SHGB) measured at week 1 and week 18</td>
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<td>Beer TM, 2010. Multiple measurements used: 1) hot flash reduction as mean measurement 2)Hot flash related Quality of Life Measurement 3)Pittsburgh Sleep Quality Index 4) Biomarkers including Morning Serum Serotonin, Urinary 5-HIAA, CGRP</td>
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<tr>
<td>Bokmand S, 2012. Hot flash frequency Sleep score Serum estradiol levels</td>
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<tr>
<td>Filshie J, 2005. 50% or greater reduction in hot flash frequency - 79% met this criteria</td>
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<tr>
<td>Frisk J, 2008. Frequency of hot flashes</td>
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<tr>
<td>Hervik J, 2009. Number of hot flashes per day, KI Kupperman Index</td>
</tr>
<tr>
<td>De Valois BA, 2010. Main measurement of outcome was frequency of hot flashes and night sweats. Secondary outcomes were measured from the Women’s Health Questionaire (WHQ) and the Hot Flashes and Night Sweats Questionnaire (HFNSQ).</td>
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<tr>
<td>Walker EM, 2010. Primary outcome measurement was hot flash frequency</td>
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<tr>
<td>Frisk J, 2009. Measurements included: frequency of hot flashes, a standardized “measurement of hot flash distress,” a hot flash score, CGRP measurements, and testosterone.</td>
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This article is focused on breast cancer patients who concurrently received Tamoxifen in their care, and who were experiencing vasomotor symptoms, including hot flashes, as a result of their medication. The authors start their paper by stating that vasomotor symptoms are the most commonly reported side effects for women taking tamoxifen, with as many as 65% to 80% of women experiencing effects. The need for better treatment alternatives for this side-effect is highlighted by the high incidence of vasomotor symptoms. It is commonly thought that low levels of estrogen and high FSH are correlated to vasomotor symptoms. At the time of the study the authors state that there were no studies previously done to see if acupuncture affects hormonal levels, but it is suggested as a possible mechanism of action.

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<th>Outcome Measurement</th>
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<td>Frequency of hot flashes</td>
<td>A baseline measurement was taken, then measured at 7 days, 14 days, 21 days, 28 days; then post treatment measurements: day 35, week 6, week 12 and 6 months from baseline.</td>
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Deng G, 2007. Frequency of hot flashes: A baseline measurement was taken, then measured at 7 days, 14 days, 21 days, 28 days; then post treatment measurements: day 35, week 6, week 12 and 6 months from baseline.
The study included 84 patients, with a mean age of 58. There were two treatment groups: true acupuncture and sham or “control” acupuncture. The sham procedure was completed by using a Park Sham Needle from Dongbang manufacturing. This type of needle is used in a variety of acupuncture studies as a control method. In this particular study the Park Sham Needle was used at 1 cm distance from the actual acupuncture points used in the study. It is stated that the needle was placed but the sham device does not allow for actual penetration to the skin itself. The acupuncturist in the study is described as a physiotherapist with 5 years of experience. However, we do not know what sort of training or additional education this physiotherapist has in relation to acupuncture, acupuncture theory or acupuncture procedures.

Points for the study were selected according to “previous reports and from expert opinion, as found in standard acupuncture textbooks.” For the true acupuncture group the physiotherapist used 0.25x40mm Dongbang needles. The needles were inserted and revolved until a sensation was achieved and felt by the patient. The depth of needle insertion was between 5 and 20mm, with a 20 minute total duration for needle retention. Additional stimulation was done at 10 minutes. These treatments were performed at an out-patient clinic, and “no relaxation accommodations were used,” implying that the environment did not include confounding factors such as relaxation music or additional conversation with the provider which could potentially add to the placebo effect. Treatments were given 2x/week for 5 weeks.

Of the 84 initial participants, 74 completed treatments with 90% compliance in true acupuncture, 86% compliance in sham acupuncture group.

There were two primary endpoints: self reported frequency and intensity of vasomotor symptoms; secondary measurements of circulating levels of estradiol, progesterone, testosterone,
prolactin, Follicle stimulating hormone (FSH) and Luteinising hormone (LH) and Sex hormone binding globulin (SHGB) were made at week 1 and week 18.

The results of the study were as follows: 42% in the intervention group reported improvement in hot flashes after 6 weeks, and 47% in the control group. In the intervention group, 55% had reduced sweating at 6 weeks, 47% in the control group. There were no statistically significant differences between the two groups. The authors found no significant differences between hormone level measurements between the control group and the true acupuncture group.

The authors of the study state that there is lacking evidence that “true” acupuncture is better than a control where. However, they do discuss at length that the control may or may not have had a null effect. It is possible that the dermal stimulation may have also contributed to the outcome possibly. “The true challenge is to find a scientifically approved control group on a waiting list for a limited time not so long as to introduce placebo effect due to positive expectations and not too short jeopardizing testing the null hypothesis.” 17

This study is compelling in its outcomes. Though the results do suggest that true acupuncture may have a positive effect on sweating in chemotherapy care, it must also be noted that the number of participants in the study limits the scope and breadth of conclusion that can be drawn. The number of participants in the study was too small to demonstrate a statistically significant effect.

This study focuses on acupuncture for men who are experiencing hot flashes as a result of treatment for prostate cancer. The authors discuss treatment options for prostate cancer patients, which are relatively limited and normally involve the use of hormones if possible. Unfortunately, there are additional risks inherent with the use of hormonal intervention. The authors do note and discuss the reality that there is very limited research in the area of treatment for hot flashes in the prostate cancer population. There are two systematic reviews noted in the literature on acupuncture, and both of these conclude by suggesting that further research be completed.

The study completed was a single-arm, Phase II study. The endpoint of the study was a 50% reduction in a hot flash score after 4 weeks treatment on a self-reported and standardized hot flash index. The study engaged multiple measures for outcomes, including the Hot Flash Daily Interference Scale, Pittsburgh Sleep Quality Index (PSQI) and a general Health Survey. As additional secondary measures there were blood and urine samples collected to see if there were noted changes in serotonin, 5-HIAA, and plasma CGRP (Calcitonin Gene-Related Peptide) levels through the course of the acupuncture intervention.

The total sample size for the study was relatively small at 25. The inclusion criteria included men being treated for prostate cancer, with bilateral orchiectomy, and the use of gonadotropin-releasing hormone agonist or antagonists with or without an anti-androgen therapy. The men had to have an initial baseline score of 4 on a hot flash inventory.

There was no randomization completed within the study, as all participants received treatment. The acupuncture protocol was based on a pilot study completed in Sweden. The authors cite in their text that the points used were from a “classic text of acupuncture,” but
Fundamentals of Chinese Medicine by Wiseman is cited. This text does reference classical acupuncture protocols, but it is uncertain what the authors mean by their statement. The acupuncture was performed by “a qualified practitioner.” Nothing else is stated about the practitioner, so it is difficult to know the experience and expertise of the practitioner.

The individual treatments were 30 minutes in length, with needling and then manual stimulation at 10 minute intervals. There was electrical stimulation done at BL23 and 32. Additionally, there was the unilateral placement DU20, HT2, PC6, LR2, SP6. No specifications were given to the side of the body used for these unilateral points. There was no description of the electrical stimulation performed in relation to mili-amp vs. micro-current frequencies, or whether or not there was alternating or consistent frequencies used in the treatment. The treatments were performed 2 times per week for 4 weeks, and then the frequency was reduced to once per week for 6 additional weeks for a total of 10 weeks of treatment. Some additional instructions for care were included based on basic dietary suggestions to limit caffeine, spicy food, and alcohol.

There was no control in the study and all patients received treatment. There were a total of 25 patients in the study, and 22 completed the entire course of the treatment. Outcomes were measured in the form of multiple variables, and these included a measurement of a hot flash score. The mean hot flash score was reduced to 60% of baseline after 4 weeks of treatment, and 52% of baseline after 8 weeks of treatment. The largest difference was observed at 7 weeks of treatment, where it was 55% of baseline. Hot flash related Quality of Life scores were measured at week 4 and week 10, with an observed improvement from 35.9 to 18.4. At 10 weeks this score regressed slightly to 22.6. The Pittsburgh Sleep Quality Index was measured, and a
global PSQI score greater than or equal to 5 is consistent with severe sleep problems. The PSQI scores moved in a positive direction but were not statistically significant. It was noted that those that responded most to treatment had more dramatic change in the Sleep Quality Index. Finally, some biomarkers were measured including the morning serum Serotonin levels, urinary 5-HIAA, and CGRP (Calcitonin Gene-Related Peptide). All of these secondary measures are suspected in the involvement of hot flashes, but the exact mechanism of action is not entirely understood.

The mean hot flash scores reduced 60% in first 4 weeks, and were at 52% of the baseline scores after 8 total weeks of treatment. The Hot-Flash-Related Quality of Life scores improved with a P=.002 value after 4 weeks of treatment. This same measure slid very slightly at 10 weeks to a P=.003.

For the measurement of PSQI (Sleep Quality Index) there was a favorable trend towards improvement, but the value P=.08 was determined from results, meaning no statistical significant difference was determined between baseline measurements and measurements further along in the study. However, there was a significant difference seen between “responders” to acupuncture and “non-responders.”

“Responders” in comparison to “non-responders” is described by the authors as the difference between those patients who demonstrated the greatest improvement in hot flashes versus those that did not note changes in hot flashes. This was explained as a correlation in which those participants that noticed the most improvements in relation to their hot flash reduction also reported the greatest improvement in sleep quality. Those two measures were, possibly, not independent of each other. No statistical difference was found in levels of Urinary 5-HIAA, or CGRP (Calcitonin Gene-Related Peptide).
The greatest limitation of the study is that it is not a controlled trial, and only had a one-arm design. However, the size of the study suggests it might have been a feasibility pilot, and a larger controlled trial is needed since the results were significant. Regardless, all patients with acupuncture had measurable decreases in urinary 5-HIAA concentrations, and it was correlated that those with the greatest reduction in hot flashes experienced the largest measurable decreases in 5-HIAA levels. The other biomarker, serotonin, did not change significantly through the course of the study. A limitation with 5-HIAA measurement is that the assessment of blood levels for neurotransmitters may not be the most accurate.

The authors state in their conclusion that: “results have suggested a clinically meaningful benefit of acupuncture in the treatment of hot flashes. The hot flash-related quality of life and sleep quality data strengthened these results and have illustrated the potential of successful hot flash therapy to improve cancer survivorship. The clinical activity of acupuncture, as observed in the present study, was comparable to SSRI antidepressants but less than that of hormonal agents such as megestrol acetate and estradiol.” The study does point to the potential that acupuncture may be a helpful addition for care of this population, specifically noted in improvements in frequency and intensity of hot flashes affecting quality of life and sleep.

This study explores sham versus “true” acupuncture in the treatment of menopausal symptoms in women undergoing treatment for breast cancer. The authors note in their introduction that breast cancer patients have much higher incidence of hot flashes and sleep disturbances due to several factors. One factor noted is simply the incidence in relation to the average age group experiencing the majority of breast cancer diagnoses (where the average is commonly noted as being between 50-70). A second explanation for these symptoms is the possible withdrawal from the use of hormone therapy in treatment. The authors point out that, unfortunately, the exact pathophysiology involved in hot flashes is not understood completely. They suggest that it is likely a multi-factorial process that involves several different aspects of the body’s homeostatic mechanisms. Additionally, they highlight that the physiology of acupuncture is not completely understood either. They highlight that acupuncture may be related to hormone regulation in the body, or possibly correlated with a decrease of calcitonin gene-related peptide levels which have been observed to spike in episodes of hot flashes. They refer to a meta-analysis from 2009 that was inconclusive on this condition, and due to the conclusions of this meta-analysis they state the need for more investigational studies.

The study included 94 women with a mean age of 61 years. The inclusion criteria for participation in the trial were women being treated for breast cancer with self reported hot flashes, and difficult or disturbed sleep resulting from the hot flashes. They excluded women who were receiving treatment with hormone replacement therapy or any women who had known metastatic disease. There were three total groups randomized for the study: Acupuncture (31 patients), Sham Acupuncture (29 patients), and an additional control group receiving no treatment (34 patients).
Randomization for this study was performed by using a sealed envelope technique with selection based on the three groups of patients. There was blinding involved in the study. Acupuncture versus sham acupuncture was blinded for both the patients and the investigators. Unfortunately the rationale of the acupuncture point selection is not described. There was no variation of the treatment from patient to patient, and there is not an adequate description of the acupuncturist delivering the treatments. It simply states “experienced acupuncturist” in the text, but there is no additional qualifying descriptors to better understand who was involved in the treatment.

The acupuncture points used in the study were: PC 6, KI 3, SP 6, and LR 3. The group receiving sham acupuncture had four pre-determined, non-acupuncture points in the “same region as the true points.” The sham procedure did involve penetration of the skin, though the needles were only used at 1 cm depth, and described as “superficial” insertion. The treatment time for both acupuncture and sham acupuncture groups was 15-20 minutes. Patients received one treatment per week for five weeks. The authors do not include any description of the setting, or if there were any additional details of the treatment environment itself. We assume there are no additional treatment recommendations such as lifestyle or dietary advice, as this was not described in the text of the study.

The authors write: “A significant effect was found on hot flashes in the acupuncture group after the second acupuncture treatment. The effect lasted for at least 12 weeks after the final acupuncture treatment, when registration was ended. In the sham-acupuncture group no significant effect was seen in comparison with the no-treatment group, but a visual trend of reduced symptoms was noted. A statistically significant positive effect on sleep was shown.
among those treated with acupuncture compared to those receiving sham acupuncture and no treatment.”

This finding was based on subjective reporting. Objectives measures were not statistically relevant, as there were no observed increases or decreases in plasma estradiol levels related to acupuncture.

Many women receiving treatment for hot flashes have the additional risk of negative side-effects from receiving hormone replacement therapy. Though there was no effect observed in this study showing any changes in plasma estradiol levels, it has been demonstrated in previous studies that acupuncture treatment may increase plasma estradiol.

The authors report in their conclusions that this study shows that correctly administered acupuncture has a clinical and noteworthy effect when compared to both a sham treatment, as well as compared to a group receiving no treatment. They conclude that acupuncture “significantly relieves hot flashes and sleep disturbances in women treated for breast cancer. The effect was seen in the therapy period and at least 12 weeks after acupuncture treatment ceased.”

Of course, this study shows that further research should be pursued to better understand the physiological process involved in improvements, as it may not be related to estradiol levels, but rather, other mechanisms involved in temperature regulation.

This is an interesting study looking at the possibility of self-treatment with acupuncture for patients experiencing hot flashes from oncology care. The authors suggest the importance of this study design as it could lend itself to a low cost, long-term care solution for this population. The authors describe that one theory regarding vasomotor symptoms is a possible increase in serotonin levels. Serotonin levels have been observed at higher levels when patients experience hot flashes and vasomotor symptoms. The regulation of serotonin may be a contributing factor in reducing hot flashes by way of the hypothalamus, and understanding the mechanism of action could be very helpful for prostate and breast cancer patients undergoing oncology care.

Hormone changes from the use of tamoxifen in treatment can frequently lead to menopausal symptoms as well as serious disruptions in normal sleep cycles. This in turn severely affects the quality of life of these patients, and can cause “considerable distress.” Though the positive effects of tamoxifen has been proven in relation to incidence and recurrence of cancer in these populations, the side-effects are severe enough that up to 10% of patients discontinue treatment all together, and 22% describe “disabling” effects from medication. The authors of this study cite that 62% of patients in this population experience vasomotor symptoms.

Acupuncture treatment in this study was by physician referral. There was no randomization process and no control group used. This was an observational study. The patients were all treated in the same treatment environment with the same acupuncture points. Acupuncture points included SP6, LR3, LI4, and TW5 as well as two needles on the sternum. The exact location of the sternal points is not specified in the text.

The reasoning behind the points used in the study was based on clinical observation at a cancer pain clinical setting where acupuncture was already being used. One group of patients
was given instructions on how to do home therapy using the same protocol. There were shown how to use studs and intradermal tacks at SP6. The training included instructions on cleaning of the area of the point to get as close to a sterile environment as possible, and instructions on securing of the dermal tacks once they were in place. Duration of the acupuncture treatment is described in the text stating that the needles were left for 10 minutes with minimal stimulation. Unfortunately the frequency of the treatments is not described. The authors describe how some of the patients were given dermal tacks to use at home which could also affect the frequency of the treatments.

For some patients frequency could vary from weekly self-treatments in addition to hospital visits, which could be two weekly or 1, 3, or 4 per month. This is a problem for the study environment and any potential replication of the results: there was no clear standardization set for the frequency of treatment being given.

For those treatments given at the hospital Serin needles were utilized for acupuncture. The needles were 36 gauge, and inserted to 1cm in depth. The following points were uses: SP6, LR3, LI4 and TE5, and two needles were inserted to touch the periosteum on the midline of the upper manubrium. The specific location of these last two points is not clear. The needles were left for 10 minutes duration with no stimulation, meaning there was no attempt to obtain a “de qi” sensation. Some patients also used dermal tacks to prolong treatment times, but this is not described clearly in the text. Some of the treatments were self directed and self administered, as described earlier. Other treatments were completed at the hospital. The details surrounding the practitioner, including experience or qualifications, are not described. It is not clear if it was an
acupuncturist, or multiple acupuncturists, or if there were nurses or doctors involved in the acupuncture treatments.

This study included 194 total participants, of which 182 were women. The mean age of the patients was 54 years old. Patients were receiving oncology care for breast cancer or prostate cancer. The mean number of hot flashes per day at onset of treatment was 16 per day, several patients were excluded from this number because they were experiencing continuous hot flashes all day long.

Nearly all patients were part of the acupuncture experiment because they were at “last resort” phase of treatment, having failed all other treatments including medications like clonidine or venlafaxine, as well as other less utilized therapies like primrose oil, homeopathy and others not specified in the text. Of all the patients in the study, 74% were involved in doing self-acupuncture with semi-permanent acupuncture needles. The duration of the treatments were varied between 1 month to 6 or more years. The mean amount of treatment time at home was 6 months.

The authors chose the measurement of a 50% or greater reduction in hot flashes to be considered clinically useful. Of the patients participating, 79% experienced 50% or greater reduction in hot flashes. There were 21% who had less than a 50% reduction. Complications from the treatment, including home treatments, was noted as including less than 9% of the participants. All complications were minor.21

Limitations of this study include the lack of standardization for the procedure and the time frame of follow-up. The patients were not randomized, and there is no control given, but as an observational study there is not necessarily a requirement for a control. If there had been a
control group, receiving no treatment for example, this may have bolstered the outcome of the study to rule out symptom regression to the mean over time. One obvious limitation is the great variation in the amount and duration of treatments given to the patients. Some of the patients were involved in self-care for many months to years. Others did not participate in such an extended fashion. These differences make it difficult to draw significant conclusions. The authors do note that acupuncture has a good safety record with very low incidence of side effects, and the side effects that did occur were not serious. The study concludes by suggesting further studies with greater control of the variables involved in self-care and acupuncture to see if this low-cost, safe intervention, could be utilized more extensively.


The authors of this study looked to compare electro-acupuncture (EA) treatment to hormone therapy for women experiencing hot flashes as a result of oncology care for breast cancer. They discuss how the therapies for breast cancer patients, including tamoxifen, may increase the frequency and intensity of hot flashes in this population. Hormone therapy (HT) has been shown to decrease hot flashes, and improve sleep and quality of life. However, most oncologists are reluctant to prescribe hormone therapy in breast cancer patients. Therefore the authors want to explore other possible therapies for intervention. There is some evidence for a
possible link with acupuncture and an increase in central B-endorphin activity. This could improve thermoregulation and decrease vasomotor symptoms. The authors ruled out the use of an acupuncture control or the use of an attempted “sham” acupuncture control because it is most likely not an inert treatment. Therefore this study is a comparison between hormone therapy and electro-stimulated acupuncture.

This study was a randomized, controlled, international, multi-center study (utilizing three different centers in Sweden). The randomization was done via a computerized program. From that randomization 219 selected to receive hormone therapy, and 215 were placed into non-hormonal treatment of electro-acupuncture. There is very little description of the treatment given to the patients. No acupuncture points are specified. It does state that treatment was given via electro-acupuncture in both hospitals and private practices. The treatments were 30 minutes in duration, and were given 2 times per week for 2 weeks, and then changed to 1 time a week for 10 additional weeks. The treatments were administered by a physiotherapist. There were 6 practitioners involved in the research, and they were “educated and experienced in acupuncture.” Other descriptors of experience or training are omitted.

The authors refers to a previous study done by Wyon. It is likely that this study may contain more details around the acupuncture protocol used in this research, but this is not stated in the text of the article.

Of the women who completed 12 total weeks of treatment with electro-acupuncture, there was a significant decrease in number of hot flashes measured over the total 24 month period, but the changes did not outperform the group receiving hormone therapy for treatment. The Kupperman Index score was utilized, and this showed that both groups had “persistent,
significant effect over time, with HT (hormone therapy) having the stronger effect” when measured at 12 and 24 months. The main measurement outcome was the reported frequency of hot flashes. Measurements were taken at 0, 3, 6, 9, 12, 18 and 24 months.

In this study it was found that electro-acupuncture relieved vasomotor symptoms in most breast cancer patients, however it did not outperform hormone therapy and did not tend to lead to long term results as seen at the 24 month follow-up period. This does seem to counteract the idea that this is a result of placebo only, as the results lasted much longer than 3 months, just less than the 24 month final follow-up. “Although EA seems to be a promising alternative, HT is more effective than EA in decreasing the number of flushes and distress they cause.”

The authors do go on to explain, however, that even though the hormone therapy group outperformed the electro-acupuncture, there is evidence from the HABITS study that there may be an increased recurrence of breast cancer in women that receive hormones as treatment, especially when compared to non-hormonal interventions such as acupuncture. The authors note that no women were adverse to receiving treatment via acupuncture in this study, and most were interested in alternatives to standard care. Overall the study does suggest that acupuncture is a safe alternative for vasomotor symptoms experienced by breast cancer survivors.

This article, from Hervic et.al in *Breast cancer research and treatment*, described the rationale for studying acupuncture in this context, as acupuncture had previously been studied for postmenopausal women experiencing hot flashes. In the introduction there is a description of hot flashes, especially in their affects and their relationship to altering of the quality of life for women experiencing breast cancers. Hormone Replacement Therapy (HRT) is controversial, though it continues to be used frequently. It is stated that anti-estrogens used in postoperative treatment of estrogen receptor positive tumors can cause hot flashes. In fact, as many as 80% of women experience hot flashes as a result of the use of Tamoxifen for treatment (an anti-estrogen agent). Some positive effects have been observed using acupuncture in the health of post-menopausal women, therefore the authors see the need for exploring this option within the breast cancer population.

There were 59 post-operative women with breast cancer involved in the study. All were documented as using Tamoxifen for 3 or more months, currently experiencing hot flashes, and all were confirmed as being post-menopausal. The patients were randomized. The exact form of randomization for the patients is described as a process using a sealed envelope technique to determine if patients would receive either traditional acupuncture (TA) or sham acupuncture (SA).

The number of hot flashes for both day periods as well as night periods was recorded for each patient for a total of 4 weeks prior to the onset of treatment. Measurement was also completed during the treatment, and again at the 12 week period after treatment. A standardized measure, the Kupperman index (KI), was also established as a baseline measurement point, again at the end of treatment, and at 12 weeks after treatment sessions. The KI incorporates various
factors of menopausal symptoms including hot flashing, sweating, sleep problems, depression, fatigue, dizziness, palpitations, joint pains, headaches, and dryness.

The report indicates a TCM style was used. There was no variation of the treatment given to the patients. The rationale described in the text was to promote cooling through the body via clearing heat and tonifying yin points. It is stated that all the points were found via sensitivity/motor points/trigger points.

The points used in the study were: LR3, GB20, LU7, KI3, SP6, RN4, PC7, LR8. Sham acupuncture treatment was described as involving the same type, gauge and length of needles. These needles were placed 2-3 mm of depth and insertion was done at 8 points 5-15 cm proximal to the upper border of the patella. The needles themselves were .30mm in length, but not described in relation to the gauge. The article does state that disposable needles were used for the study, though it can be assumed that all research currently utilizes disposable needles due to regulations. The needles were manipulated by hand until the patient reported: “dull ache, radiating or tingling sensations felt.”

The total needle retention for treatment was 30 minutes, and treatments were given 2 times per week over the course of 5 weeks. After that initial treatment period then there was continued treatment once per week for a final 5 weeks. This resulted in 15 total treatments for the acupuncture group and sham group.

There is not a description included regarding the setting for the acupuncture treatment, or additional treatment environment variables. The authors do state specifics regarding the acupuncturist involved, stating that treatments were performed by a Physiotherapist with 3 year
certified training from Norwegian Acupuncture School, and 15 years of practice as a Physiotherapist.

The results were that the traditional acupuncture (TA) group had a 50% reduction of hot flash symptoms during treatment, and an additional 30% reduction during the following 12 weeks after treatments ended. The sham acupuncture (SA) group had no statistically significant differences seen in hot flash frequency. Only 3 of the 28 in the SA group experienced a reduction in hot flashes. No statistical changes were observed at the 12 week measurement after treatment in the SA group.

Regarding hot flashes at night, the TA group had 60% reduction during treatment, and then an additional 30% reduction in the following 12 weeks. There were some changes seen in the SA group regarding night hot flashes. The authors recorded a 25% reduction of night time hot flashes which was statistically significant. Unfortunately during the following 12 weeks there was complete nullification of those changes. The patients quickly returned to their baseline measurements.

The authors recorded data by using two major indicators. Primarily the measurement of improvement was gauged through a measurement of mean number of hot flashes per day, and secondarily through a Kupperman Index (KI) rating. The time frame of the measurement was 4 weeks before treatment, during treatment, and then 12 weeks after end of treatment period.

The authors conclude that there are, many times, a mixed result found for trials studying hot flashes in post-menopausal women as well as breast cancer patients. However, in this study there were significant results found, especially in the group receiving true acupuncture. This was especially noted in the measurement taken 12 weeks after treatments were completed. At that 12
week marker there were continued reductions in hot flashes in the true acupuncture group compared to the group receiving sham acupuncture. In the sham group there was a reduction for night time hot flashes, but those changes were not continued at the 12 week marking point. There were no statistical changes observed between the results for the sham group in relation to daytime hot flash changes. It is a notable outcome that the nighttime hot flashes improved in both groups, but did not continue in the 12 weeks after treatment for the sham group. These results do suggest that true acupuncture potentially has a physiological effect, and is more than placebo which could describe the results seen in the sham acupuncture group. Further studies, using a robust acupuncture intervention, such as the one used in this study, are necessary to determine the true effects of acupuncture.


This study was an observational study. The authors detail that up to 80% of women taking Tamoxifen for prevention of recurrent breast cancer describe “troublesome” hot flash side effects. In the UK alone it is noted that there are nearly 46,000 new breast cancer diagnoses each year, so the relevance of managing these symptoms is important. Mechanisms of pathophysiology are not well understood. Though it is generally thought that after use of Tamoxifen for some period of time will result in a reduction of hot flashes and vasomotor
symptoms, it is shown that many women continue to experience hot flashes for over 3 of the
typical 5 year treatment period, as well as after the discontinuation of the Tamoxifen therapy.
Though there are options for treatment, including hormone replacement therapies, SSRI’s and
anti-hypertensives, many women do not want to use pharmaceutical medications. It is common
that patients find that the side effects of these medications can be disruptive.

This is a prospective, single-arm observational study which is based on a baseline
measurement, and then compares to a post-treatment measurement. The participants received 8
total acupuncture treatments over 8 weeks, and experienced a total monitoring period of 30
weeks. Measurements were taken two weeks prior to commencement of the treatment (baseline),
and then at the fourth acupuncture treatment, at the end of treatment (8 weeks), and then again 18
weeks after the last acupuncture treatment. Hot flash frequency was the primary outcome
measurement.

A self reported diary which documented 24 hour periods for 14 days was used for
patients, as well as physical and emotional well-being measurements which were the Women’s
Health Questionaire (WHQ) and the Hot Flashes and Night Sweats Questionnaire (HFNSQ).
Measurements for all three of these were taken at Baseline, 4 weeks into the treatment period, 8
weeks into the treatment, 4 week after treatment, and 18 weeks after treatment was completed.
Women were selected for the study by the following inclusion criteria: using tamoxifen as
adjunctive treatment for breast cancer, being 35 years or older, 6 or more months post active
cancer treatment which could have included radiation, chemotherapy, or surgery, and patients
were cleared of the possibility of metastatic cancer. All patients in the study had at least 6 months
of Tamoxifen use.
There was no form of randomization used in this study, as it was an observational study. The acupuncture used in this study was both a TCM style and a 5 Element (5E) style. The first treatment done was an “aggressive energy” treatment which is based in a 5-E framework. Then for the following treatments, treatment number 2 through treatment 8, the points used were based on a protocol treatment based on diagnosis of KI Yin deficiency. The points were used to clear heat and resolve dampness. The standard protocol treatments were not varied from patient to patient. It is stated that the framework for the treatment stemmed from a general literature search as well as a standard TCM protocol for the treatment of this pattern. It should be noted that this study did the protocol treatment, as well as several additional points that were “individualized points for the patient,” as determined by health history and relevant constitutional health factors.

This was an interesting and seemingly unique approach to treatment which included both a 5-E aggressive energy treatment at the first treatment, and then 7 other treatments which were based in TCM theory on Yin Xu heat, damp, and heat clearing. Though the type of needle used, as well as the depth of insertion were not specified, the authors are very specific about the treatments that were given. The 5-E treatment is described at length, including procedure and time spent with each patient. The TCM treatment included Nourishing KI Yin: LU7, KI6, Ren4, SP6; Stopping Night Sweats: HT6, KI7; Clear Heat: LI11; and Resolving Damp: SP6, LU7, LI11. Most of the points were done unilaterally instead of bilaterally, and the order of insertion and removal of the needles is clearly described in the methods section.

The number of treatments given is clearly stated as being 8, but the frequency of treatment encounters is not specified clearly. It is not clear if it was once a week, or more often, or whether or not the frequency was different for different patients’ needs.
The authors specify that the acupuncturist did give advice where it was deemed “appropriate.” This is not explained at any length or with greater detail. It describes the advice as being in relation to “eating habits, rest, exercise, and managing stress.” Setting of the treatments given is not described. It is stated the “there was no attempt to limit the therapeutic relationship.” The reader is unsure about the credentials of the acupuncturist, or the extent of experience the acupuncturist brings to the study. It is simply stated as “the acupuncturist” throughout the text.

Of the 54 initial participants in the study, 50 completed the treatment of 8 acupuncture visits. The results in relation to frequency of hot flashes and night sweating found that 45.8% of participants had a 50% or greater reduction in hot flash and night sweat frequency. Nearly 40% showed a reducing in hot flashes and night sweating, but decrease was less than 50%, and finally 12.5% of participants showed no improvement. WHQ data indicated that there were statistical improvements in the areas of Sleep Problems, Memory, Concentration, Vasomotor Symptoms, Anxiety and Fear, Menstrual Symptoms and Sexual Behavior. The WHQ index showed a clinically significant change in how bothersome hot flashes and night sweats were - this was self rated. The article notes that 85.4% of participants experienced some reduction in hot flashes and night sweats, with nearly 50% experiencing a reducing that exceeded a 50% improvement in the experienced symptoms.

This study has a wide array of limitations, though it does not render the study useless. The main limitation is the lack of a control. That withstanding, the results do show that, within a certain acupuncture setting and intervention it is possible to find significant improvements in symptoms for women experiencing hot flashes and night sweating. Additional limitations are
discussed in the conclusion of the article: several of the participants did not adhere to the 8 week treatment period, and received treatment over an additional week or two. Also, the acupuncturist had the possibility to add some acupuncture points to the protocol as necessary for individualized constitutional needs. In reality, this renders the data less impactful. However, it also alludes to some of the strengths that could further other study models which are not as effective.

Some of the strengths of this study include the versatile treatment methods employed for the women receiving treatment. This is closer to a “real world” approach to how acupuncture is done in the clinic. The authors make note that the acupuncturist made no attempts to limit patient-practitioner relationships in the clinical setting, something that might be deemed “placebo interference” in other studies. However, in the true practice of acupuncture there is a significant amount of patient practitioner interaction, and the study design better mimics what breast cancer patients would experience if they were seeking out acupuncture for their hot flashes and night sweats.

The study does highlight additional measures of improvement for common adjunctive symptoms ranging from sleep to emotional well-being, and therefore is relevant as a indicator that more studies should be performed looking at acupuncture as a possible useful intervention for the global health changes experiencing from breast cancer recovery in additional to the use of Tamoxifen for prevention.

This research compared acupuncture to the medication venlafaxine for the maintenance of vasomotor symptoms in women with hormone receptor-positive breast cancer. This article describes an incidence of 182,460 new cases of breast cancer in the US in the year 2008, and an estimation that 1 in 8 women in the US will develop breast cancer in their lifetime. Common treatment is the use of chemotherapeutic agents as well as a hormone therapy, commonly Tamoxifen. As a result of the long term treatment needed for the hormone therapy to be effective (usual course of treatment is 5 years), many women experience a decrease in quality of life and commonly experience hot flashes, night sweating and difficulty with normal sleep cycles. Though hormone therapy is commonly recommended, it can be contraindicated if there is a risk of hormone-sensitive recurrent cancer. Other therapies to attempt to reduce hot flashes include steroids, clonidine, and anti-depressants such as SSRI’s. The authors additionally cite research showing that many women are adverse to taking more medications, with some reservations about possible side-effects.

The patients in this study were recruited from oncology clinics through the Henry Ford Hospital System. Inclusion in the study was based on the following factors: a diagnosis of stage 0-III in pre- or post-menopausal breast cancer patients, active use of hormone therapy with tamoxifen, experiencing 14 or more hot flashes a week, being 18 or more years of age, having completed chemotherapy, and within 5 years of chemotherapy treatment, the current use of
hormone therapy for 4 or more weeks without plans to discontinue, and a Karnosky performance status greater than 70. All patients had a life expectancy of 6 or more months. There were 50 women recruited and assigned to either venlafaxine or acupuncture. There were a total of 25 patients in each group. After 12 weeks of treatment both groups discontinued their respective therapy and were then observed over the course of 12 months. Though women in the study were placed into two groups, the exact process of randomization is not described.

No description of the practitioner is given in the text of the article. As well, there is no description given in relation to a “style” of acupuncture. However, it does describe that each patient received BL23, KI3 and SP6 for general menopausal symptoms, and then additional points were allowed depending on diagnosis, these points were: DU14, GB20, LU9, LR3, DU20, ST36, Ren6, PC7 and HT7. There is no discussion of how many women received variations on the standard protocol/standard treatment that was being administered. The details around the type and form of needle used is very complete and very descriptive. The practitioners utilized either Seirin or Carbo needles both at a 34 gauge diameter (0.20 x 30mm). The needles were specified as being “filiform.” The needle depth when used was 0.25 to 0.5 inches deep, and there was a gentle manual manipulation of the needles used to create a *deqi* sensation for the patient. No electrical stimulation was used.

Treatments were given 2 times a week for 4 weeks, and then once a week for the remaining 8 weeks. The sessions were 40 minutes in duration, with 30 minutes of every session dedicated to acupuncture treatment. The setting for the acupuncture was described as being one of two different locations: the Henry Ford Center for Integrative Medicine as well as the Walter B. Ford Department of Radiation Oncology at Henry Ford Hospital.
The comparator/control treatment is Venlafaxine. Venlafaxine is an SSRI and is the used frequently for the “pharmacologic therapy of choice” for women experiencing hot flashes as a result of breast cancer care. Effectiveness compared to placebo showed, at four weeks of treatment, hot flash score reduction in 27% of women taking placebo and up to 61% for larger doses of Venlafaxine.

The women in the study had a median age of 55, but there was a wide range of ages from 35 to 77 years of age. The primary measurement of outcome that was being observed was the frequency of hot flashes. There were multiple points of measurement from immediately before treatment and the end of the treatment period, and then again 3, 6, 9 and 12 months out from the termination of treatment. ANOVA analysis of the data showed that in both groups there was a similar reduction in symptoms in both groups that were greater than 50% for frequency of hot flashes. There was a gradual return at the follow-up time periods towards the baseline of hot flashes observed before treatment.

There was a statistically significant increase in hot flashes after the termination period for the group receiving venlafaxine. The acupuncture group maintained a lower level of hot flashes after treatment was terminated, and that difference maintained itself throughout the 12 month follow-up period, though not as dramatic at 9 and 12 months. The authors state that both groups experienced positive outcomes in that they both had “significant decreases in hot flashes, depressive symptoms, and other menopausal quality of life symptoms.” Both groups reported improvements in mental emotional and mental health measurements. The authors found the changes to be similar enough to find that acupuncture was “at least as effective as venlafaxine.” The primary outcome measurement in this study was the frequency of hot flashes.26
Time frame given for this outcome measurement extends from baseline (pre-treatment) to post-treatment periods immediately at the end of treatment, then again at 3 months, 6 months, 9 months, and 12 months from the end of the treatment period.

This article suggests that acupuncture is at least as effective as a standard care pharmaceutical treatment, venlafaxine, thereby avoiding mistakes made in other articles where the authors deem acupuncture ineffectual without addressing the fact that acupuncture may perform just as well as other models of care. The authors take note of an unexpected outcome: the venlafaxine group there was a “rebound” like effect after treatment was terminated where the patients reported a dramatic spike in the months immediately following the discontinuation of the medication.

The acupuncture group maintained at a lower level of hot flash frequency and observed a slower return towards the mean found at baseline (before treatment was initiated). The acupuncture group continued to stay at a lower level of hot flash frequency compared to the venlafaxine group, even at 6, 9 and 12 months, though statistically speaking the results show that both interventions are nearly equal in outcomes. Improvements were also observed in additional symptoms such as depression. The authors of the study discuss why they chose not to try a comparison of acupuncture to an acupuncture control such as sham acupuncture, citing evidence that sham acupuncture way stimulate the anterior cingulated cortex and thalamic regions of the brain (as seen through fMRI), possibly showing that sham acupuncture is not an inert control in comparison to acupuncture. The authors call for more research to be done, as well as the exploration into acupuncture for vasomotor symptoms in men who are prostate cancer patients.

The authors of the study discuss that prostate cancer is the most commonly diagnosed form of cancer in men. Many men receive surgical or medical castration therapy for prevention of reoccurrence, but as a result of these treatments up to 80% of men experiencing disruptive hot-flashes as a side effect to care. Traditional treatment approaches include SSRI’s, gabapentin, clonidine and several other medications, but many of these medications carry serious side-effects. Therefore, the authors suggest that there is room for exploration and development of alternatives for the treatment of men experiencing these side-effects.

The authors discuss that acupuncture is a possible treatment, and may have some effects in the regulation of the central nervous system as well as the regulation of serotonin and B-endorphins in the brain. A possible disregulation of the hypothalamus may be at the root of the hot flash symptoms, and may result from a lack of sex hormones circulating in the body from the oncological treatment used. The temperature set point in the body can be altered, and vasodilation as well as sweating can be a response to attempted body temperature regulation. A possible mediation of this response may occur through the regulation of the body’s levels of calcitonin gene-related peptide (CGRP). It is observed in higher levels in men experiencing hot flashes. There are previous studies that show a decrease in CGRP in 24-hr urine samples takes
from women with hot flashes who have received acupuncture. This study is aimed to explore two
types of acupuncture in relation to men with hot flashes.

This study was performed in Swedish medical centers. The patients were recruited from
urological outpatient clinics. Only male patients complaining of hot flashes and a history of
chemical or surgical castration 3 or more months prior, and experiencing 20 or more hot flashes a
week, were allowed to join the study. Exclusion was based on patients receiving hormone
treatments that were not of a “GnRH analogue,” the use of psychotropic drugs, or other
alternative medications that might have implications or effects on hot flashes.27

The treatment description is very detailed. There were periods of treatment which were
30 minutes in duration occurring twice a week for 2 weeks. After the initial 2 weeks of treatment
there was a continuation of treatment once a week for a 10 week period. The patients would
receive treatment in a side-lying position. Twelve needles were always used, with needle length
and diameter being 0.25mm by 15mm or 0.30mm by 30mm. All points were inserted between 5
and 20mm at predetermined acupuncture points, and then “twirled to evoke needle sensation.”
The authors state that the rotation of the needle “reflects activation of muscle nerve afferents.”
Some points did receive electro stimulation (BL23 and BL32) at 2Hz, this was only completed
for the group receiving this treatment variation.

The rationale for the point selection is not provided. It is explained that the treatments
were not varied from patient to patient. The study compared traditional or standard acupuncture
to an electro-acupuncture treatment where the same points were used. The only difference
between the groups is the use of electro-acupuncture performed at BL23 and BL32 bilaterally.
The treatment setting was both in larger hospitals as well as private practices. There is limited information on the treatment environment, though the authors state that the practitioners were instructed very specifically to not discuss the effects or the treatment with the patients receiving treatment.

This study was randomized between the two treatment groups. Randomization was done via envelopes with a note indicting the treatment category. The acupuncturists involved in the study received the envelopes with a note indicating the treatment being provided for the specific patients involved in the study. There is not a description of the practitioners involved in the study. It is only written that “treatment was given by a physiotherapist.” There were a total of five practitioners used for the study. Since this was not a controlled trial there were two groups used, and the comparator in this study is acupuncture with electro-stimulation compared to acupuncture without electro-stimulation.

The measurements for outcomes included the frequency of hot flashes experienced by the patients, a standardized measurement of “hot flash distress,” a hot flash score calculated from the first two measures, CGRP measurements, and testosterone. The time-frame of outcome measures involved multiple points: Baseline, 4 weeks, 8 weeks, 12 weeks, 6 months, 9 months and 12 months.

Patients had significant reduction in frequency of hot flushes per 24 hour periods after 4 and 8 weeks of treatment. Statistically the hot flush reduction was significantly reduced at 12 weeks, 6 months, and 9 months. After 12 months the change was no longer statistically significant, suggesting a return to baseline levels of hot flashes. There was not a significant difference between the two groups of patients - traditional acupuncture and electro acupuncture
were statistically similar enough that it was impossible to determine if one was more effective than the other. “Distress from flushes” was calculated for each group at each of the treatment intervals, and in concordance with the frequency of hot flushes it was reduced from 4 weeks of treatment all the way to 9 months post treatment. At 12 months the change was no longer statistically significant. The hot flush score was reduced 78% in the electro acupuncture group, and 73% in the traditional acupuncture group. This may suggest electro acupuncture is possibly more effective, but further studies and comparisons with larger patient populations would be needed to determine if this was statistically significant or not. Measurement of CGRP was inconclusive. Though numbers were reduced in both groups, the differences were not significant enough to merit conclusions drawn from the data. Testosterone levels changed as measured through the course of treatments, but the changes were not dramatic enough to be statistically significant.

The authors suggest that this is the only known published study on acupuncture for prostate cancer patients who have received castration treatment and are experiencing hot flashes. The frequency and distress caused by hot flashes were significantly reduced in both the traditional acupuncture group as well as the electro acupuncture group. The greatest limitation of this study is the exclusion of a placebo or control group (even a non-treatment comparison group). The authors did not feel it ethical to have a group not receive treatment, even though that would have bolstered the impact of the study itself. There was a type of control found through the observational period that preceded treatment. The patients recorded hot flash frequency and distress for hot flashes was calculated during the observational period. It is noted that during this observation period there was no significant changes or modifications seen in symptoms, and
when compared to changes noted at 4 and 8 weeks into treatment there is a statistically significant improvement which suggests that the acupuncture was more effective compared to a no treatment control period.

There are studies which have explored the use of placebo alone for men with hot flashes, and it has been shown to have a 20-30% reduction in frequency of hot flashes, but the effects of the placebo never last more than 3 months from the start of the treatment, indicating that the 9 months or more of changes observed in this study suggest that acupuncture is more than a placebo. There has been evidence that CGRP, measured in urine, can be reduced in women experiencing hot flashes. Those results were not replicated in this study. The authors suggest that these results may have been hindered by methodological and practical problems with collecting urine specimens from the men in the study. The authors conclude that acupuncture is a possible option for treatment of hot flashes in men who have prostate cancer, and note that there were no serious side effects as a result of the treatment provided. The study needs to be duplicated with a larger population and also include a control group for comparison.


Hot flashes are defined in the introduction as increased temperature with additional vasodilatation and sweating. Additional symptoms may include anxiety, difficulties with sleep,
and heart palpitations. Women may experience hot flashes when treated for breast cancer, and as many as 2 of 3 female patients will report hot flashes, with a significant number of these patients describing the hot flashes as severe. Notably, a common treatment is estrogen replacement therapy, but this is somewhat controversial due to possible aggravation of health risks including strokes and increased risk of breast cancer. Though there are several natural therapies that have been investigated, none have produced studies with results which are clinically sound. Acupuncture is being investigated in this context, that of a sham control vs true acupuncture for treatment of hot flashes in breast cancer patients.

The study was a randomized controlled trial comparing sham acupuncture to verum, or “true” acupuncture. The treatment period was 4 weeks, with patients receiving 2 treatments per week. A total of 19 acupuncture points were used, based on standard textbooks and expert opinion, and the same 19 points were used for all patients without a Chinese Medical diagnosis or pattern differentiation. Both sham and true acupuncture was performed by experienced acupuncturists. The sham treatment involved a retractable needle made in Germany which has previously been used as a control for other acupuncture studies. The primary measurement between groups was the frequency of hot flashes. This was measured in a self-reported fashion. The patients would complete a one day diary recording the number of hot flashes experienced. This was done at a baseline measurement before treatment was initiated, and then again at days 7, 14, 21, 28 and 35.

Patients again recorded hot flash frequency at 6 weeks post treatment, and then again at 26 weeks post-treatment. One interesting aspect of this study included patients rating credibility of the treatment itself, ranked immediately after the first treatment. This was done to try to
determine if participants were able to distinguish “real” treatment from sham treatment. This
exact protocol was not observed in any other studies for this review.

Randomization of patients was achieved by using a computer generated system which
allowed complete concealment of patient placement. Acupuncturists were not blinded to the
allocation of patients, as performing a true or sham treatment is impossible to do blinded. The
patients and all involved in patient care and research in the study were completely blinded to
group allocation.

The treatment is detailed as including DU14, GB20, BL13, PC7, HT6, KI7, ST36, SP6
and the auricular points of shen men and the sympathetic nervous system point. The rationale of
the treatment is described in the following way: “This prescription was derived from previous
reports and expert opinion, as found in standard acupuncture textbooks.” The treatments were not
varied.

The true acupuncture group was treated with Serin needles from Japan sized 0.20 x
30mm. The needles were inserted 0.25 to 0.5 inches into the skin. The needle was manipulated
by hand, no electrical stimulation was used on the needles. The practitioners manipulated the
needles to obtain a de qi sensation. The needles were then left for 20 minutes, and then removed.
Some patients did not receive all the acupuncture points if it involved needling an arm with
lymphedema. The frequency of treatment was twice a week for 4 weeks. There were a total of 8
treatments completed.

The sham needle was created by Asiamed in Germany, and it is stated that previous
studies had been done using the same type of sham needle. The needle was previously shown to
have high ratings of patient credibility rating, meaning that patients rated the device as seemingly like acupuncture.

There were no details given regarding additional interventions or modalities used with the patients. There is minimal description of the treatment setting, stating that there was a massage table used, and eye pillows for all patients to help with the process of blinding and control treatment, which was a sham acupuncture technique. The acupuncturists had at least three years of postgraduate education, and all had continuous work experience ranging from 3 years to 25 years.

For this study there were a total of 72 participants who were randomized. Of that total 67 completed the treatment through to the end point of the study. Both groups, sham acupuncture as well as true acupuncture, experienced a 20% reduction in hot flashes in the first two weeks. After that point the sham group did not report any significant improvements, but the true acupuncture group experienced an additional 10% reduction in symptoms. Though the true acupuncture group reported few hot flashes compared to the placebo/sham acupuncture group at the end of the treatment period, the difference was not enough to merit statistical significance. An interesting difference in this study was the transfer of the placebo group to true acupuncture after the treatment period was complete. Patients who completed the sham acupuncture treatment period were then moved and given true acupuncture starting from week 7. These patients experienced an additional decrease in hot flash frequency when measured at the end of the true acupuncture treatment period. That reduction was around 20% in reference to hot flash frequency. Additionally, both groups maintained their improvements in hot flash reduction at a 6 month measurement period after the completion of the treatment. The researchers also measured a
credibility score in relation to the treatment itself, and the scores were nearly equal. This suggests that blinding of the patient groups were successful. Results were taken at the following time measurements: baseline measurement was taken, then measured at 7 days, 14 days, 21 days, 28 days; then post treatment measurements: day 35, week 6, week 12 and 6 months from baseline.

The authors note that both groups experienced a reported reduction in hot flash frequency, and that reduction was greater in the true acupuncture group compared to the sham acupuncture. However, the difference was not enough to reach statistical significance. They also note that the sham group did experience improvements after being moved to a true acupuncture treatment, which may suggest that true acupuncture may have more of an effect than sham acupuncture. Again, statistically speaking the difference is not enough to state definitively.

Though there are several pilot studies that are cited by the authors, they point to conflicting outcomes from the presented literature. Unfortunately this article does better answer unanswered questions regarding sham and true acupuncture, notably that there were differences between the groups themselves, and continued improvement when sham acupuncture was changed to true acupuncture. The authors note that there are several confounding variables involved within their research. First and foremost, it is entirely possible that a sham acupuncture treatment is not a null stimulus, and in this case the sham needle did not penetrate the skin but did replicate the sensation of a needle being used for acupuncture. The points used for the sham treatment were near to acupuncture points used for actual “true” acupuncture, and there is no way to be sure that these points are not physiologically active.

The authors cite Kaptchuk in their research showing that both true and sham treatments may lead to overall relaxation, which in turn could result in a reduction in hot flashes.29 The
authors describe additional limitations in their research: a possible lack of the best possible acupuncture intervention as the same treatment was given to all patients, the limitation inherently involved with self-reported data measures (frequency measures of hot flashes), and a limited understanding of whether or not the duration of the intervention was sufficient or not.

The authors postulate that possibly extending the treatment period for acupuncture, resulting in a greater total amount of treatments given, may have resulted in a greater reduction in hot flashes. Given our lack of understanding about “dosing” of acupuncture in the treatment setting, it is difficult to know if 8 treatments was appropriate or not, and difficult to know if an extended treatment period of two months and 20 treatments would have had a much more profound (and possibly statistically significant) outcome in patient data.


This is a systematic review of RCT clinical trials that was limited to those comparing acupuncture to sham acupuncture interventions. The authors of this article did a comprehensive search from inception of database to August 2008, including MEDLINE, CINAHL, EMBASE, PsychoInfo, as well as 5 Korean Databases, 4 Chinese Databases, and the Cochrane Library. Inclusion was limited to human patients, breast cancer patients, needle acupuncture, and where only hot flashes were being treated (meaning no other adjunctive or co-occurring conditions). Articles were read via independent reviewers and calculated three criteria for the articles:
randomization, blinding, and withdrawals of participants in each of the studies. Then a point system was used to rank the articles using 95% confidence intervals and the Cochrane Collaboration’s software.

Initially there were 67 articles identified, 61 were eliminated due to exclusion criteria. Six RCT’s met the final inclusion criteria. Outcomes from the systematic review found three different RCT’s comparing effects of manual acupuncture to some type of sham acupuncture, though the sham treatments are not specified in the review. One of these articles found positive outcomes, two other were failed to demonstrate statistically significant outcomes. Two meta-analysis were included in the review, both showed positive effects of acupuncture in comparison to sham (where P=0.005 or below).

The review included several other studies, though they did not rank these studies within their own systematic review. They noted an RCT which compared EA with hormone replacement therapy, and another which compared venlafaxine to acupuncture but had a null outcome.

Finally, the authors refer to a RCT which compared applied relaxation to acupuncture, but did not have an outcome showing a difference between each group. It should be noted that none of these final articles mention the comparison of acupuncture to a standard of care for breast cancer in relation to positive outcome or result. If a RCT showed that both venlafaxine and acupuncture resulted in the same outcomes, then that is actually something to note as positive for acupuncture, as it is meeting the standards of a typical Western intervention. It would be, therefore, as good as a standard care intervention for hot flashes in women.

The authors of the study point out that there are very few sham controlled RCT’s, and also point out that there are contradictory findings amidst the studies themselves. They “fail to
provide convincing evidence for the effectiveness of acupuncture,” or that the acupuncture therapy is better than other standard interventions, including hormone replacement therapy. However, the article does not mention or highlight that where there is no significant difference between standard therapy and acupuncture it also implies that acupuncture is as good as standard interventions, such as hormone replacement therapy.

The authors of the article state that their only limitations stem from poor research and poor results presented from the current research that has been completed. At this time they say there is no significant evidence indicating that acupuncture is a valid intervention, but further studies are necessary to determine if there is a possibility of having acupuncture at the table for future treatment.

Frisk J. Managing hot flushes in men after prostate cancer—a systematic review.


This article is a systematic review focused on men experiencing hot flashes from the hormonal treatment of prostate cancer. The article outlines the importance of understanding this type of cancer, namely that it is the most widely diagnosed cancer for men, with incidence around 219/100,000. There is evidence that this cancer is increasing in prevalence with increasing rates being observed between 1997 and 2007 in several studies. An additional factor is that this cancer is normally found in men 65 and old, and the number of men in this age category is going to increase exponentially in the coming years.
A common therapy for men undergoing prostate cancer care is to receive androgen deprivation therapy, to decrease testosterone which furthers the growth of cancer cells in the prostate. A common side effect of androgen deprivation therapy is hot flashes. The exact cause and mechanism by which hot flashing occurs in this illness is not completely understood, though it is thought to be similar to the mechanisms observed in women experiencing hot flashes - serotonin alterations, noradrenalin alterations, and beta-endorphins alterations leading to possible instability in the set-point for body temperature in the hypothalamus. This may cause sweating and vasodilation in the body’s attempt to down-regulate temperature.

Up to 80% of men being treated for prostate cancer experience hot flashes, of those who did experience hot flashes 70% still had them 5 years after treatment, and 40% had them 8 years after treatment. The results of the systematic review are described, and of 252 articles identified, reviews, meta-analyses, and studies that were not deemed relevant were excluded. This resulted in the identification of 32 studies involving treatment (from 1983 to 2009) and of those, 5 were appropriate for the inclusion criteria.

Most of the studies involved various pharmaceutical interventions, but this systematic review does discuss acupuncture. The authors cite one pilot study which included 7 men with hot flushes receiving traditional acupuncture 2x/week for 2 weeks and then 1x/week for 10 weeks. Results found 74% reduction in frequency of hot flashes at 10 weeks, and greater than 50% reduction at a three month evaluation after the study. No side effects reported. Another study randomized between traditional acupuncture and electro acupuncture following the pilot study’s time frame of treatment (2x/week for 2 weeks and then 1x/week for 10 weeks). Reduction in
frequency of hot flashes greater than 50% was reported by 78% of EA group and 73% of TA group.

Additionally, a study involving traditional acupuncture was cited where 194 patient with hot flashes and cancer then used the treatments at home for up to six years, and found 79% had a 50% or greater reduction in hot flashes. There was one study involving 60 men compelling treatment with auricular acupuncture 1x/week for 10 weeks and found a significant decrease of 70% for both day and night sweats, with intensify reduced by 50% for day and 63% for night sweating.

The article’s authors reports that “acupuncture studies lack a proper placebo control. This is a problem in any acupuncture research, since no placebo method yet seems to be fully physiologically inert. However, some studies show promising results, with an effect on hot flushes stronger and longer lasted than that produced by placebo pills, and have reported few side-effects.” This statement does highlight the core of the issues seen within acupuncture studies, namely the difficulty found with control and a lack of a truly inert control for acupuncture research. As well, the article highlights the fact that acupuncture is found to be safe intervention, with rare side effects seen from research involving treatments. The article also states that research “results indicate that it may be as effective as SSRI’s/SNRI’s, with only minor side-effects.”

After a thorough review of all of the articles that met the inclusion criteria for this systematic review in relation to hot flashes there is not a strong, clear, or decisive conclusion that can be drawn. Certainly, it is clearly demonstrated that acupuncture has the potential to be of
help for oncology patients experiencing hot flashes. There are several studies which
demonstrated positive effects of acupuncture for this population. When comparing these studied,
it is possible to state broadly that those studies with a more robust treatment design, which
clearly differentiated and thought out the point intervention used, had a tendency to show better
results (CITE). Another conclusion that can be drawn is that those interventions which included a
varied treatment option for the participants in the study had a tendency to show improved
outcome measures. The majority of the studies adhered to a strict point protocol, often limited in
point selection and scope, and this lack of variation may have impacted the final results
negatively. From an acupuncturist perspective, the ability to vary and match a treatment to a
particular patient’s syndrome picture is extremely important.

The basis of an acupuncture intervention revolves around arriving at a clear diagnosis
which is based on specific symptom differentiation. Different patients presenting with the same
general condition, in this case being defined as hot flashes, have a potentially dramatic difference
in their treatment based on the additional symptoms that are occurring concurrently with the hot
flashes. Though the design of research for acupuncture is being discussed within the
communities of acupuncturist practitioners, the improvements needed are not widely observed.
This was evident in the systematic review which attempted to isolate the most recent studies
from the past 10 years. In conclusion, there are signs of potential for acupuncture to play a role in
the treatment of hot flashes in oncology care. However, as a body of evidence seen here, there
are significant discrepancies between the studies that were reviewed. This leads to a lack of clear,
definable conclusions. As with much of the ongoing research that occurs in many fields, the
clearest revelation that this systematic review elucidates is the need for more research, and
dialogue around what compromises worthwhile and meaningful research in the field of acupuncture.

7) Review of Articles on Acupuncture for Xerostomia in Oncology Care

The parameters of the systematic review on research articles on acupuncture in the care of oncology related xerostomia yielded four articles. Two systematic reviews of the literature which had been previously published were also reviewed to broaden the base of knowledge on this condition.

Xerostomia is a common condition resulting from oncology care for patients who are experiencing oral and neck cancers. The use of radiation treatment at the local tissue in the oral cavity leads to damaged and impaired salivary capacity as well as mucosal irritation and inflammation, which leads to a dry and sticky oral cavity. Patients frequently describe these changes as debilitating, severely painful in some cases, and constantly interfering with eating normal foods, drinking thicker liquids, and having the ability to taste and enjoy foods. Treatments commonly include anti-fungal agents, corticosteroids, and a large variety of oral hydration products that are cream or gel based which attempt to replicate a normal sensation of hydration in the oral cavity.\(^\text{39}\)

In the review of acupuncture for oncology related xerostomia the same STRICTA guidelines were used to gain a sense of the quality of the acupuncture intervention in the specific studies. Two of the four articles that met inclusion criteria included a description of the specific style of acupuncture being used. Three of the four articles specified the reasoning, or gave specific references for the treatment being used for the patients with oncology related
xerostomia. Additionally, those same three articles also included some variation to the treatment protocol. As was discussed in the section on oncology related hot flashes, treatment variation is a sign of a stronger treatment intervention due to the principles of acupuncture.

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<th>Acupuncture Rationale</th>
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<tbody>
<tr>
<td>Meng Z, 2012.</td>
<td>NO</td>
<td>NO</td>
<td>NO Variation</td>
</tr>
<tr>
<td>Cho JH, 2008.</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Simcock R, 2013.</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Meng Z, 2012.</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
</tbody>
</table>

The four articles for oncology related xerostomia had a relatively strong presentation of the details around the needling interventions given. All described the number of needle insertions used, the names and locations of the points used, and whether or not a response was sought for the points being used (also referred to as de qi in much of the literature).

Only the article by Cho, 2008, described the exact needle type that was utilized for the study, however this same research failed to describe what time of needling stimulation was used, and failed to detail the needle retention time for the patients in the study. Three of the four articles describe the depth of needle insertion. The article by Simcock, 2013, fails to describe
needling depth. As a whole this section appears to be strong for these four articles, especially in comparison to the counterpart section described for acupuncture in relation to hot flashes in oncology.

<table>
<thead>
<tr>
<th>Details of Needling</th>
<th>2a) Number of needle insertions</th>
<th>2b) Names/Location of points used</th>
<th>2c) Depth of insertion</th>
<th>2d) Response sought</th>
<th>2e) Needle stimulation</th>
<th>2f) Needle retention time</th>
<th>2g) Needle type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meng Z, 2012.</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Cho JH, 2008.</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>Simcock R, 2013.</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Meng Z, 2012.</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

All four of the articles in this systematic review describe the treatment regimen to great depth. They all discuss the number of treatment sessions given to the patients in the studies, as well as the frequency of treatment sessions and the duration of the treatments given. There was a large variation between the different studies themselves in relation to the treatments given. There were two articles published by Meng, both in 2012. These two present with similar research design. In the first research design the treatments were given three times a week for six weeks,
coordinated with the frequency of the radiation treatments being performed. In the second article by Meng the frequency is again matched with the radiation procedures being used for the oncology patients in the study, though over a longer period of seven weeks versus six. The study by Cho, 2008, had treatments given over 6 weeks, twice a week. Finally, in the Simcock, 2013 study there was a reduced frequency of treatment at one per week over the course of eight total months.

<table>
<thead>
<tr>
<th>Treatment Regimen</th>
<th>3a) Number of treatment sessions</th>
<th>3b) Frequency and duration of treatment sessions</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meng Z, 2012.</td>
<td>YES</td>
<td>YES</td>
<td>Treatments were done 3 days a week, at 20 minutes, for 6 weeks which coincided with the 6 weeks of radiation treatments being given. This totaled 18 treatments. In the sham group the treatments were exactly the same.</td>
</tr>
<tr>
<td>Cho JH, 2008.</td>
<td>YES</td>
<td>YES</td>
<td>Treatments were done twice per week for 6 weeks. The sessions were said to be 20 minutes long.</td>
</tr>
<tr>
<td>Simcock R, 2013.</td>
<td>YES</td>
<td>YES</td>
<td>There were 8 total treatments, done once per week over two months. The sessions lasted 20 minutes.</td>
</tr>
<tr>
<td>Meng Z, 2012.</td>
<td>YES</td>
<td>YES</td>
<td>Duration of treatment was stated to be 20 minutes. The frequency of the treatment is stated as 3 days per week for a course of 7 weeks. The frequency of treatments were matched with the frequency of radiation treatments for the patients involved in the study.</td>
</tr>
</tbody>
</table>

In relation to other components of treatment, such as moxibustion, dietary and lifestyle advice, or herbal interventions, the study by Simcock, 2013 provided detailed description of
They did not allow moxibustion or other aspects of Chinese medicine. However, it was interesting to note that part of the study design included providing the patients with detailed information about self-care for xerostomia, such as the use of gels and creams that support oral hydration. The three other articles did not provide specific information regarding the details of additional treatment components in the research design, or failed to discuss the context and setting of the acupuncture treatments given.

<table>
<thead>
<tr>
<th>Other Treatment Components</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Other components of treatment</td>
<td>4a) Details of other interventions administered to the acupuncture group (e.g. moxibustion, cupping, herbs, exercises, lifestyle advice)</td>
</tr>
<tr>
<td>Meng Z, 2012.</td>
<td>NO</td>
</tr>
<tr>
<td>Cho JH, 2008.</td>
<td>NO</td>
</tr>
</tbody>
</table>
Under the STRICTA analysis of practitioner background all but one of the articles reviewed did include a detailed description of the practitioners involved. In the Meng studies from 2012 the description of the practitioner is the same, possibly suggesting that the same individual was used in both studies. The most complete description of the practitioners involved was included in the Simcock article from 2013. In that particular study all the practitioners were

<table>
<thead>
<tr>
<th>Other Treatment Components</th>
<th>4a) Details of other interventions administered to the acupuncture group (e.g. moxibustion, cupping, herbs, exercises, lifestyle advice)</th>
<th>4b) Setting and context of treatment, including instructions to practitioners, and information and explanations to patients</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simcock R, 2013.</td>
<td>YES</td>
<td>YES</td>
<td>Other modalities and types of interventions were not allowed, including moxibustion and other aspects of Chinese medicine. However, the patients did receive two educational sessions which included the etiology of xerostomia, effects on daily living, preventative research, dietary advice, symptomatic relief products such as gels, and oral hygiene advice. The material was standardized so all patients received the same information in the same way. The context of the treatment is within a group setting, but details as to the instructions to practitioners is not described. Finally, in regards to the acupuncture intervention, it is not stated if explanations were provided for patients in relation to theory or possible mechanisms by which acupuncture could be helpful (or previously completed research).</td>
</tr>
<tr>
<td>Meng Z, 2012.</td>
<td>NO</td>
<td>NO</td>
<td>The patients were treated in a seated position, but there is no description of additional information or interventions for the acupuncture group (ie moxabustion or lifestyle and diet recommendations). There is no description of instructions for practitioners, or explanations for the patients in the study.</td>
</tr>
</tbody>
</table>
selected based on membership with the British Acupuncture Council. Additionally, all of these acupuncturists underwent specific training in workshops designed to further the practitioners knowledge and understanding of the protocol being used in the study. The intention of this procedure was to increase the consistency in the implementation of the treatment between the different groups receiving treatment.

<table>
<thead>
<tr>
<th>Practitioner Background</th>
<th>5) Description of participating acupuncturists (qualification or professional affiliation, years in acupuncture practice, other relevant experience)</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meng Z, 2012.</td>
<td>YES</td>
<td>The author notes that all treatments were done by the same practitioner, and that practitioner had over 35 years of experience.</td>
</tr>
<tr>
<td>Cho JH, 2008.</td>
<td>NO</td>
<td>There is no description or statement regarding the acupuncturist or person performing the interventions (sham or true acupuncture).</td>
</tr>
<tr>
<td>Simcock R, 2013.</td>
<td>YES</td>
<td>The acupuncturists were all members of the British Acupuncture Council or an equivalent group, and all were required to attend workshops where the protocol being used was described in detail for consistency between treatment groups.</td>
</tr>
<tr>
<td>Meng Z, 2012.</td>
<td>YES</td>
<td>The practitioner is described as having hospital credentials, and is said to have over 35 years of experience.</td>
</tr>
</tbody>
</table>
In the four articles that met inclusion criteria for this systematic review there was one study that used a sham device. This research designed included the Park sham device, which was also observed in some studies related to hot flashes where a sham device was included in the research design. The exact location and use of the sham device is clearly described in the research article, though none of the points used are considered standard acupuncture points as they were located slightly off of standard point locations described in TCM texts. The research article by Cho from 2008 also used locations approximating textbook acupuncture point locations. Instead of a sham device however, they used true acupuncture needles inserted very superficially at the designated spots.

In the final two articles reviewed for acupuncture care in radiation-induced xerostomia there was a similar control design. The Simcock research from 2013 and the second article by Meng from 2012 both have standard oral care and hospital procedure for xerostomia as the comparator group. In these two research protocols, the participants that were not receiving acupuncture treatments were able to receive standard education and procedures used for xerostomia. Typically this includes hygiene recommendations around cleaning and hydration, as well as information around other alternatives for mouth dryness such as gels and creams which can be applied throughout the day to maintain a sense of oral hydration. These standard procedures are commonly used in hospitals for xerostomia patients, though commonly patients report that the benefits that result from this type of care are temporary. It is also noted in the literature that some of the very products designed to support oral care may have the potential to cause additional
side-effects, such as increased irritation and inflammation of the oral mucosal tissues which are damaged from the radiation exposure.  37-39

<table>
<thead>
<tr>
<th>Control or Comparator Interventions</th>
<th>6a) Rationale for the control or comparator in the context of the research question, with sources that justify this choice</th>
<th>6b) Precise description of the control or comparator. If sham acupuncture or any other type of acupuncture-like control is used, provide details as for Items 1 to 3 above.</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meng Z, 2012.</td>
<td>YES</td>
<td>NO</td>
<td>The sham needle was a Park non-penetrating needle device, which is mentioned and used in other studies that compare sham to real acupuncture. The exact locations of the points are very clearly defined in the text of the article. There were four locations used: one point below Ren24, one point radial and proximal to SJ6, one point between LI7 and LI8, and one point distal and lateral to ST36. In the sham group there were additional ear points used, with the placement of true acupuncture needles only the helix of the ear. Additionally, GB32 was needled to elicit de qi sensation in the control group.</td>
</tr>
<tr>
<td>Cho JH, 2008.</td>
<td>NO</td>
<td>YES</td>
<td>The sham points were “non-acupoints 2 cm away from the real acupoints.” At these spots on the body the same needles were used except that they performed a more superficial insertion of the needle in comparison to the real acupuncture points.</td>
</tr>
<tr>
<td>Simcock R, 2013.</td>
<td>YES</td>
<td>YES</td>
<td>The comparator treatment is standard oral care and education given for patients experiencing xerostomia. Patients either started treatment in the acupuncture group, or started treatment in an oral care group. At week 8 both groups finished their treatments and measurements were taken. At week 13 there was a crossover of patients into the alternate group. The acupuncture group started oral care for 8 weeks, and the oral care group received acupuncture.</td>
</tr>
</tbody>
</table>

The authors describe xerostomia as a serious and inhibitive side effect to radiation treatments common to patients receiving radiation therapy for head and neck cancer. It is suggested that up to 100% of patients experience some degree of dryness of the mouth, which may significantly impair a cancer patient’s quality of life. In addition to dryness, or xerostomia, patients may also experience changes in taste, a loss of normal appetite due to difficulty with processing and masticating foods, difficulty with swallowing and with sleep. To date treatments are palliative and include lozenges and gums, or substitutes for saliva. Previous studies are varied

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<th>6a) Rationale for the control or comparator in the context of the research question, with sources that justify this choice</th>
<th>6b) Precise description of the control or comparator. If sham acupuncture or any other type of acupuncture-like control is used, provide details as for Items 1 to 3 above.</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meng Z, 2012.</td>
<td>YES</td>
<td>YES</td>
<td>The control group received standard hospital care for xerostomia. This group did not receive any additional or special information regarding xerostomia. They did receive a standard oral hygiene education which is how hospitals treat and work with this population.</td>
</tr>
</tbody>
</table>
in outcome, showing positive changes for this population but varied in treatment approach and no research to date with a sham or controlled arm of the study. This study was done as a follow-up from a previous feasibility study, and the authors propose to test participant reaction to true vs sham acupuncture with the hypothesis that acupuncture will reduce or prevent the development of xerostomia for head and neck cancer patients undergoing radiation treatment.

The study was a 2-arm study where patients were randomized and treated in a true acupuncture group as well as a sham acupuncture group. The IRB’s included MD Anderson Cancer Center as well as the Shanghai Cancer Center of Fudan University. All the patients were recruited through the Fudan University Hospital. Inclusion in the study was determined by age, active nasopharyngeal carcinoma diagnosis with scheduled though not yet having started IMRT radiation therapy, as well as having no alteration or limitation of the parotid and submandibular glands. If the patients had any history previously of xerostomia or possible physical limitation or closure of the salivary glands, they were excluded from the study. Patients were required to be acupuncture naive. Any patient having received alternative treatment or any biomedical drug that could affect the salivary function were excluded from the study. Measurements were based on the Xerostomia Questionnaire, which is previously validated in other research studies. Scores range from 0 to 100, and a score equal to or less than 30 indicated mild to no symptoms of xerostomia. Higher scores correlate with moderate and severe symptoms. Additional measurements were used via the MD Anderson Symptom Inventory Head and Neck (MDASI-HN), which rates severity of symptoms as well as factors of disturbance in daily activities as a result of symptoms presented. This measurement was validated and shown to be “highly
reliable.” Finally, additional measurements included the use of unstimulated and stimulated slyery flow rates.

Patients were randomly assigned to two groups - G1 and G2. G1 received true acupuncture at a frequency of 3 days per week for a 6 week total duration of treatment. The G2 group had the exact same schedule, but was given sham treatment instead of true acupuncture.

The points used were of “standard recommendation,” but it does not describe what the standardization was or what the criteria were for selection of those points. Treatment was performed in a supine position. Point location was selected via “standardized techniques,” and included Ren 24, LU7, KI6 and the ear points: Shenmen, Point Zero, Salivary Gland 2-prime, and Larynx. All points were done bilaterally, except for Ren 24 which is located along the midline. All needles were inserted to the standard recommended depth, though this is not explained clearly in the text and it is assumed they are referring to standardized text book descriptions of depth and point location. Patients in the true acupuncture group also received one “sham needle” at GB32 to maintain blinding of the procedure. Treatments were done 3 days a week for 6 weeks which coincided with the 6 weeks of radiation treatments being given. This totaled 18 treatments. In the sham group the treatments were exactly the same.\(^{33}\)

There were no additional recommendations given to the patients, and the context of the treatment was not described in any way. It does state that the practitioner was credentialed to work in a hospital setting, so we could potentially assume that the treatments were done in a hospital but it is not explicitly stated. The author notes that all treatments were done by the same practitioner, and that practitioner had over 35 years of experience. The sham needle was a Park non-penetrating needle device, which is mentioned and used in other studies that compare sham...
to real acupuncture. The exact locations of the points are very clearly defined in the text of the article. There were four locations used: one point below Ren24, one point radial and proximal to SJ6, one point between LI7 and LI8, and one point distal and lateral to ST36. In the sham group there were additional ear points used, with the placement of true acupuncture needles only the helix of the ear. Additionally, GB32 was needled to elicit de qi sensation in the control group.

There were multiple measurement tools used: XQ - Xerostomia Questionnaire; the MDASI-HN - MD Anderson Symptom Inventory Head and Neck; Unstimulated Salivary Flow (UWSFR) and Stimulated Salivary Flow (SSFR). Measurements were taken at weeks 1, 2, 3, 4, 5, 6 and 11.

Completion rates within the study were relatively high. One patient in the sham group stopped receiving treatment. Blinding was assessed and both groups reported believing that they were receiving true acupuncture. The XQ data showed statistically significant improvement in scores under 30 (meaning low to no symptom presentation) that was only in the true acupuncture group. This improvement continued through week 11, which was the final measurement point. The MDASI (symptom severity analysis from MD Anderson) showed no statistical difference during the first 2 weeks of treatment. From week 3 through week 6 the differences were statistically significant, especially in the Head and Neck quality of life measurement. It was seen that the control group had a much higher score indicating a higher proportion of symptoms compared to the true acupuncture group. Finally, saliva flow measurements (called Sialometry) showed no statistical difference between the two groups in UWSFR and SSFR (stimulated and unstimulated measurements).
The authors state that at the date of publication it is the first randomized, sham-controlled study that was performed at the same time as the course of radiation therapy. They note differences emerging between the two groups starting at the third week, and found that the positive changes found were still present 1 month after ending the treatment. When comparing the sham group to the true acupuncture group, 25% of those in the true acupuncture group reported xerostomia symptoms 1 month after the end of radiation treatments. In the sham group nearly 90% reported ongoing symptoms. Though the authors note that sialometry measures were inconclusive this limitation may be due to the small size of the samples used, as well as inconsistencies inherent in the measurement equipment. The authors point to possible biomedical mechanisms involved in observed increases in blood flow to the parotid glands following acupuncture, as well as observed increased concentrations of vasoactive substances in the saliva itself found in previous studies. Finally, they conclude that the results and findings of this trial should be taken with some caution as the group size was relatively small. There is a call for more research with larger population sets to determine the feasibility of this treatment for xerostomia.


The authors reference the need and importance of this type of study as radiation-induced, or radiotherapy-induced xerostomia is a serious problem which affects the quality of life for many patients with head and neck cancer. Additionally, substitutes for saliva and other palliative
treatments are frequently referenced as having limited efficacy in the clinical setting. Acupuncture is still somewhat controversial due to the lack of a described mechanism of action, as well as the lack of objective data in this category of treatment.

Patients were recruited with a history of radiotherapy over a minimum dose to specific glands for head and neck cancer, as well as current symptoms and quality of life change due to xerostomia. Any patient with metastases or ongoing inflammatory disease that required treatment was excluded. Twelve subjects were selected and placed into two groups: real acupuncture and sham acupuncture. Measurements were taken for whole saliva secretion as well as subjective measurements for quality of life. This measurement was used in other studies, the Xerostomia Questionnaire. Randomization was done through a block method. This method is stated, but not clearly described.

The acupuncture was based on commonly used points in Korean Acupuncture Clinics for xerostomia, it was not varied from patient to patient. The points are described as being based on “theoretical meridian actions supporting…water-like elements of the body belonged (sic) in yin.” The authors note needle depth of 1.5cm for all points in the real acupuncture group. In the sham acupuncture group needling was still performed, but only to a depth of 0.5cm. There is no description of the needle retention, nor is there any description of the manipulation done to the needles, if any was performed. The type of needle was described as a Korean type needle, 0.20mm by 30 mm in length. Treatments were done twice per week for 6 weeks. The sessions were said to be 20 minutes long. There were no descriptions given in regards to any additional modalities given, or what the setting of the treatment was. There is no description or statement regarding the acupuncturist or person performing the interventions (sham or true acupuncture).
The sham points were “non-acupoints 2 cm away from the real acupoints.” At these spots on the body the same needles were used except that they performed a more superficial insertion of the needle in comparison to the real acupuncture points.

The outcomes were based on Salivary Flow rates in an unstimulated and stimulated measurement. The researchers also used the XQ - Xerostomia Questionnaire, which is a standardized and subjective measurement of patient’s salivary rates. Measurement were taken at baseline (0 weeks), 3 weeks, and 6 weeks.

There were changes in both the real acupuncture group as well as the sham acupuncture group. Only the real acupuncture group made statistically significant improvements within its own cohort, when compared between their baseline measurement and the 6 week measurement. Between the sham acupuncture and the real acupuncture groups there was not enough of a change to meet statistical significance, this was despite the fact that salivary flow rates increased in the real acupuncture group and decreased in the sham acupuncture group. Though this indicates that real acupuncture had more of an effect, it is not enough of an effect for the authors to claim that real acupuncture was better than sham. In the XQ measurement (Xerostomia Questionnaire) the real acupuncture group significantly improved their score by 2.33 points. The sham acupuncture group only improved their score by 0.33 at the 6 week measurement period. Much like the salivary flow rates, the differences between the groups led to a support for real acupuncture as possibly being more effective than sham acupuncture, but the difference again did not reach statistical significance. The authors note in the results that there was an expected low statistical power due to the small number of subjects included in the study.
The authors discuss in the limitations of the study due to the small sample sizes included for the outcomes reported. They also note that the randomization process placed extra weight, or burden of proof, on the real acupuncture group. This occurred by way of an uneven distribution of patients into the two groups. The real acupuncture group had a much longer median time post-radiation therapy at 35.5 months, compared to 6.5 months in the sham acupuncture group. It is thought that the longer a patient experiences these symptoms the more difficult and recalcitrant those symptoms are to reverse. Second, the disease-state characteristics of each group were not evenly spread. At the baseline measurement the real acupuncture group reported 2 times greater reduction in salivary flow compared to the sham acupuncture group. As well, the XQ scores were much higher (a correlation we would expect to find if there is greater salivary inhibition). The XQ score for the real acupuncture group was 13.5, whereas the sham acupuncture group only reported an average of 7.7. The authors conclude: “we found a tendency toward therapeutic efficacy of acupuncture for radiotherapy-induced xerostomia. Our study had some limitations for clear validation of the effects of acupuncture on radiotherapy-induced xerostomia, because of the small number of subjects. Nevertheless, this study should contribute to new strategy for the care of quality of life in patients with radiation-induced xerostomia.”

The authors detail the importance of studying complementary and alternative medicine for xerostomia within the head and neck cancer population. Radiation-induced xerostomia, or dry mouth, is very prevalent within the cancer population receiving treatment for their cancer or who have receiving treatment in the past. It is suggested that at five years post-radiation treatment period, nearly 50% of patients continue to experience debilitating symptoms which significantly interfere with quality of life. As noted in other studies: chewing, swallowing, speaking and sleeping are the most common areas where problems arise because of this condition. Therapies are relatively limited. Oral care is offered by nurses at hospitals and includes education and palliative care to improve quality of life. Some oncologists prescribe pilocarpine, but only about 1/3 of oncologists are comfortable doing so because of the lack of data and seriousness of side-effects that can occur from this medication. It is observed that the use of complementary and alternative medicine is already fairly prevalent, at over 20% of patients experiencing xerostomia (this number is based on data obtained in the UK). These complementary and alternative interventions include herbal remedies, vitamins, and relaxation techniques. Acupuncture is possibly helpful for this population based on various pilot studies that are published for this population of patients. This study is based on a pilot study by the same core authors which used a group treatment setting with an acupuncture protocol developed in the US.

The study followed a randomized crossover design. Patients had to meet inclusion criteria: having been treated with radical radiotherapy, experiencing xerostomia and being recurrent free of cancer for more than 18 months. Exclusion included any history of heart disease, bleeding disorders, history of problems with recurrent infections, and phobias that involve needles. It was also confirmed that the needling sites were accessible on every patient,
meaning there were not areas of reconstructive or prosthetic surgery inhibiting the possibility of an acupuncture treatment. There were two interventions used. One was the use of oral care sessions. Nurses specialized in oral care offered two education sessions each lasting 1 hour given 1 month a apart. Materials and presentations were standardized between each group. The information given included the etiology of xerostomia, effects commonly experienced for daily life and research on prevention that was current at the time of the presentations. The second session was focused on dietary advice, oral hygiene and products that are available for palliative relief of xerostomia (this includes saliva products, gels and others). The alternate group received group acupuncture sessions that lasted 20 minutes and occurred over 2 months, once per week for a total of 8 treatments. The points used are described in the STRICTA review.

Randomization was done with an independent statistician. A mixed randomization method was used. Crossover between each group occurred 4 weeks after the end of the first intervention.

Treatments were not varied from patient to patient. There was not a particular style of acupuncture performed, but the rationale of the treatment was based on previously used protocol for this condition, as well as the addition of one point because of advice given by the British Medical Acupuncture Society. Details of the needling include the following: 0.2 x 7mm needles were used on auricular points Salivary Gland 2, Point Zero, and Shen Men; 0.16 x 25mm needles were used on body points which included LI2 and LI20. The depth of insertion is not described clearly, but it states, “needles were inserted to dermis.” The retention time for the needles was 20 minutes, and there was manual stimulation done at 10 minutes to obtain a de qi sensation at the points. Other types of stimulation were not allowed. The patients were in a group setting for
treatments. There were 8 total treatments, done once per week over two months. The sessions lasted 20 minutes.32

Other modalities and types of interventions were not allowed, including moxibustion and other aspects of Chinese medicine. However, the patients did receive two educational sessions which included the etiology of xerostomia, effects on daily living, preventative research, dietary advice, symptomatic relief products such as gels and crease, and oral hygiene advice. The material was standardized so all patients received the same information in the same way. The context of the treatment is within a group setting, but details as to the instructions to practitioners is not described. Finally, in regards to the acupuncture intervention, it is not stated if explanations were provided for patients in relation to theory or possible mechanisms by which acupuncture could be helpful (or previously completed research). The acupuncturists were all members of the British Acupuncture Council or an equivalent group, and all were required to attend workshops where the protocol being used was described in detail for consistency between treatment groups.

The comparator treatment is standard oral care and education given for patients experiencing xerostomia. Patients either started treatment in the acupuncture group, or started treatment in an oral care group. At week 8 both groups finished their treatments and measurements were taken. At week 13 there was a crossover of patients into the alternate group. The acupuncture group started oral care for 8 weeks, and the oral care group received acupuncture. Measurements were taken at baseline, 5, 9, 13, 17, and 21 weeks. Primary outcome measurement is improvement in dry mouth, objective salivary flow measurements were taken as well.
Participant completion was very high, 144 of the 145 recruited finished the course of treatment. Seventy patients were in the acupuncture group (followed by oral care), and 75 patients were in the oral care (followed by acupuncture). Severity of symptoms between each group was statistically significant at the end of the first treatment period (meaning the acupuncture group received 8 treatments over 8 weeks, and the oral care group received two sessions at one month separation). The areas where statistical significance was found included “sticky saliva,” the need to sip to swallow food, and waking at night needing to drink water. Moderate evidence found that acupuncture was more likely to relieve dry lips compared to oral care alone. There was not a statistical difference found in the need to sip liquids to relive a dry mouth. Saliva measurements were taken in each group for both stimulated and unstimulated salivary flow. It was found that there was not a statistically significant difference between the oral care group and the acupuncture group.

The authors conclude that there is significant evidence that acupuncture may be useful for relieving the symptoms of xerostomia, most notably in the severity of dryness experienced, the stickiness of saliva, the need to sip fluids in order to swallow foods, and in needing to wake at night to drink water. The study failed to link subjective improvements in xerostomia with objective salivary flow measurements. However, the authors note the difficulty in correct and useful measurements of salivary flow as they may vary significantly between individuals as well as vary in the same individual. Therefore, they do conclude that “subjective sensations of oral dryness are not reliable indicators of measurable flow rate.” The authors note that there significant challenges in the long-term care of patients who have had head and neck cancers, especially in relation to xerostomia which present with significant changes in quality of life.
measures. Useful treatments to date are very limited, and oral care does not treat the condition in a lasting and meaningful way. Unfortunately the mechanism of action for acupuncture, or understand how acupuncture could be helpful, is not completely understood. The authors postulate, in reference to other research, that a central nervous system pathway may be involved, as well as a neurotransmitter or neurohormonal release as plausible mechanisms for the benefit seen in acupuncture. For xerostomia itself, it is postulated that there might be a stimulation of residual glandular tissues, or that increased blood flow to areas of minor salivary glands may increase overall sensations of saliva in the mouth and upper gastric tract. The authors describe why they did not use a “sham” arm within the study. There are significant difficulties determining a sham acupuncture treatment that is not physiologically active. Indeed, some fMRI studies show that “sham techniques have demonstrated brain activity similar to that seen with real needling.” In fact, the authors cite a study that showed that use of the acupoint LI-2 in healthy individuals showed, with fMRI, the activation of specific regions of the brain. For this reason, they chose to use the two interventions included in the study. The strengths found in the study include the replicability of the interventions, as well as the randomization of the patients within the different treatment arms. There were clear differences seen between each group, and there was significant evidence that acupuncture had more of an effect than standard oral care interventions given to this population. Finally, the use of group treatment sessions gives another avenue to treatment, as they are greater in feasibility and accessibility for patients.

The authors start the article by noting that a vast majority of patients who have to undergo treatment for head and neck cancers develop xerostomia which, in turn, vastly inhibits quality of life measures. Symptoms do not tend to improve on their own. Additionally, patients are at a higher risk for oral complications due to xerostomia, such as a higher rate of dental caries as well as infections due to the imbalance of natural oral bacterial flora. It is noted that salivary glands are particularly sensitive to radiation therapy which is used for head and neck cancers. A reduction in the flow of saliva is measurable within several days of the onset of radiation therapies, and by the end of 6 weeks there may be as much as 80% reduction in salivary flow. Currently there are treatments used for xerostomia, but all are palliative. These include lozenges, different types of gum, and saliva substitutes. The drug pilocarpine has been used, but shows limited success. Other drugs, such as amifostine, are used but include serious side effects. Other treatments that have been attempted include electrical stimulation of the tongue and the palate, and hyperbaric O2 therapy. These options have not proven helpful. There are limited reports which have shown acupuncture to be a possible solution for improving quality of life for this population, including a trial by these same authors which included sham needling in comparison to true acupuncture. There are no studies, however, that compare outcomes when acupuncture is given concurrently with radiation treatment, effectively testing whether or not acupuncture could
halt the progression and development of xerostomia when administered at the same time that radiation treatments are given.

Eighty six patients were randomized to 2 different groups. The inclusion criteria were patients being 18 or older, having been diagnosed with nasopharyngeal carcinoma with current and intact parotid and submandibular glands, and a Zubrod performance status of 0-2. Exclusion was based on any previous history of xerostomia, any suspected or confirmed physical closure of the salivary ducts in the mouth, any present of bleeding disorders or current use of warfarin, and the use of any other drugs or herbal medicines that could potentially affect the salivary functions. Group 1 received acupuncture 3 times per week for 7 weeks on the same day that they received radiation therapy. Group 2 did not receive acupuncture, they did receive standard care for xerostomia patients which included oral hygiene recommendations. Measurements were taken via sialometry (saliva measurements) and self-reported data via the Xerostomia Questionnaire and the MD Anderson Symptom Inventory-Head and Neck (MDASI-HN) which is a validated instrument for this population. The Xerostomia Questionnaire was the primary outcome measurement, as it has been validated repeatedly across multiple cohorts and studies previously conducted. Salivary flow was measured both in unstimulated and stimulated flow rates, and followed procedures used in a previous study by the same authors. Measurements were taken at baseline, once per week for 7 weeks of treatments, and then at 1 month and 6 months after the termination of the study.

The points were selected according to previous reports and studies done, TCM point indications, and the anatomical and neurovascular regions and tissue associated with the points. The treatments were not varied between patients. The authors describe how they did attempt to
reduce the number of needles being used, and made the attempt to “identify those that integrate TCM theory and biomedicine.”

The points included in this study were: Ren 24, LU7, KI6, and auricular points Shenmen, Point Zero, Salivary Gland 2, and Larynx. All points were bilaterally placed except for Ren 24. Treatment duration was 20 minutes. In regards to stimulation of the needles, standardized techniques were used for both point location as well as the depth of needle insertion. There was the attempt to achieve a de qi sensation at the points used. Duration of treatment was stated to be 20 minutes. The frequency of the treatment is stated as 3 days per week for a course of 7 weeks. The frequency of treatments was matched with the frequency of radiation treatments for the patients involved in the study. The patients were treated in a seated position, but there is no description of additional information or interventions for the acupuncture group (ie moxabustion or lifestyle and diet recommendations). There is no description of instructions for practitioners, or explanations for the patients in the study. The practitioner is described as having hospital credentials, and is said to have over 35 years of experience.

The control group received standard hospital care for xerostomia. This group did not receive any additional or special information regarding xerostomia. They did receive a standard oral hygiene education which is how hospitals treat and work with this population.

Baseline measurements were taken for all patients, and then patients were randomized to either Group 1 or Group 2 using a random number table. The study identified 127 eligible participants, 86 were included in the process of randomization and completion of the treatments. Patients were randomized and then compared between demographics and medical history. It was found that the groups were comparatively balanced among these variables. Completion of
treatments in Group 1 for acupuncture was very high at 82% completion. Of the 18% that did not complete the entire course of care, many received much of the complete course of treatment. Of the 86 initial participants randomized for the study, 62 completed the 6 month follow-up evaluation. Non-completion of the follow-up included patient dropout, death, and inability to return to the medical center. The primary outcome measure (XQ) a statistically significant difference was found over time between Group 1 and Group 2. The control group reported higher levels of xerostomia compared to the acupuncture group, and that difference maintained statistical significance at the 6 month re-evaluation period. When measured in relation to having a score greater than or less than 30 (it is standardized that scores below 30 on the XQ demonstrates clinically relevant reduction of xerostomia to a mild level or no symptoms of xerostomia), statistical significance was most prominent at weeks 11 and again at the 6 month follow-up period. Results from the MDASI-HN demonstrated that the control group had greater severity of symptoms which became statistically significant starting at weeks 3 and 4, continuing at the week 11 measurement, and continuing at the 6 month follow-up period. In the sialometry measurements a statistically significant difference was found in unstimulated whole salivary flow starting at week 3, continuing through week 11. At the 6 month followup the difference was still present but no longer of statistical significance. The stimulated whole salivary rate was statistically different from week 4 of treatment through the week 11 measurement. At the 6 month followup it was found that the difference was still statistically significant.

The trial showed measurable differences between a control group of standard care for xerostomia patients, and the acupuncture group. Differences were observed through the study in the Xerostomia Questionnaire, the MD Anderson Symptom Inventory as well as measured
salivary rates for both stimulated and unstimulated states. The authors note the importance of the XQ results regardless of the salivary flow measurements. The FDA itself uses subjective outcomes as a standard for the drug approval process for medications in relation to xerostomia. This is due to the fact that sialometry measurements are difficult to standardize. Individual to individual, these rates vary wildly, in both healthy and diseased populations. Additionally, there is no “minimum” measurement of salivary flow which then designates a determination of a state of xerostomia. The subjective state of xerostomia is the functional definition of an individual suffering from the disorder. It is noteworthy that the outcomes measurements showed improvements across both subjective and objective measurements. The differences between the groups emerged around the 3rd and 4th weeks of treatment, and these changes remained statistically significant into the 6 month follow-up period. The authors discuss the limitations of the study, namely that the exact mechanisms of action are not entirely understood. Previous studies do suggest that blood flow may change with the use of acupuncture, and specific studies suggest that the blood flow to the parotid glands could show measurable improvement with acupuncture. Other studies demonstrate a change in brain activity with the use of acupuncture for xerostomia, specifically in relation to areas of the brain where gustatory and olfactory stimulation is active. Regardless, the authors suggest that more research is needed to better understand the mechanisms of this intervention. Acupuncture itself, they point out, is an attractive treatment option due to the lack of adverse events, and the low cost involved with treatment. The authors also discuss why they chose not to use a placebo arm for a control group in the study. They note that sham acupuncture and other acupuncture placebos are not definitively inert, and finding an appropriate placebo is thus far impossible in relation to
acupuncture. Finally, the authors suggest more studies such as this one, with large groups of patients and longer follow-up periods as the results of this study suggest that acupuncture is a plausible treatment option for reduction of the severity and occurrence of xerostomia for patients with head and neck cancer.


This article is a systematic review, therefore typical components of CONSORT and STRICTA are not included here in my review. The systematic reviews of these topics are included as they offer additional insight into the role of acupuncture for cancer care. Because my review only includes article from the last 10 years of publication, the inclusion of other systematic reviews may allow for a broader view of the topic. The authors of this article discuss the importance of the topic of xerostomia due to the high prevalence of complaints from patients undergoing treatment for head and neck cancer. Though radiation treatment is paramount and central to the treatment of these cancers, there are documented decreases in salivary flow, up to 70%, that occur within the first week of treatment.

Over the typical course of treatment for cancer the total salivary flow may decrease to only 20% of baseline measures, and changes to salivary function are permanent in many cases. The management of this condition is important due to the decrease in quality of life. With these changes these patients also tend to have a higher lack of compliance with treatments. The standard
of care for xerostomia includes oral hygiene and substitutes for normal saliva. These palliative measures result in short term improvements, but do not lead to longer resolution of the xerostomia.

Additional strategies that are more invasive include the actual transfer of glandular tissue to the patient, or radiation techniques that are designed to spare the glands involved in salivation. Unfortunately these techniques show limited success. The authors go on to describe acupuncture as a possible option for intervention with this population. These have been cases of healthy patients showing increase in saliva with treatment, as well as treatment for Sjogren’s disease and some studies related to xerostomia-like populations (where radiation is the major cause of salivary gland disorder. As a result of increased usage of this alternative intervention, the authors suggest the need for a systematic review to evaluate all studies to that point in order to evaluate efficacy. The systematic review included multiple search terms and was conducted through PUBMED, EMBASE and Cochrane Library. Additional databases used searched that included Chinese publications.

Two principle researchers evaluated the articles found. They limited the studies included based on a variety of variables including the participants in the study itself, the interventions (limited to studies that involved actual “invasive acupuncture,” outcome measurements, and the type of studies themselves). There were 482 citations that were investigated, of those 427 were excluded based only on title and abstract. Fifty nine studies were reviewed in full-text form and only 4 studies were included in the final review. The final review included one study from China, one from Sweden, one from Korea and one from the US. Because of the varied methodological and clinical reporting and intervention, the authors of this systematic review ruled out the use of
a meta-analysis in order to better understand the data present. They rated the results of the methodological quality, and found that only two of the studies clearly had randomization done by computer. They state that any randomization done by other means is not adequate or appropriate for a label of “randomized.” They rated the efficacy and safety of acupuncture for xerostomia resulting from radiation or radiotherapy. Their observations were that two of the studies included salivary flow rates as the objective outcome measure, but the other studies included self-reported scores as central to their conclusions.

Regardless of the validity of the measures used, the authors say that the “potential bias and variation among the included studies” results in an inability to “positively identify the therapeutic effect of acupuncture for radiation-induced xerostomia.” It is noted that the studies consistently return with a lack of adverse effects and a high level of tolerability for the patients involved in the study. The worse side-effects mentions are slight bruising or extremely limited bleeding at the site of the needle insertion. However, the authors state that due to the small number of studies included the conclusion that acupuncture is safe is difficult to determine. Overall the authors describe and elucidate many of the ongoing problems that are established through a review of acupuncture research. Namely, there is difficulty in correctly identifying an appropriate control for acupuncture.

Though placebo-controlled design is considered the most important aspect of clinical research and clinical effects, the fact remains that acupuncture has been difficult to replicate in a placebo form without having any effects on the patient. There is a wide variety of placebos used in studies, but “no consensus has been reached on the standard placebo control setting in acupuncture research.” The authors suggest that the sham acupuncture device from Streitberger
and Kleinhenz may be the most appropriate for studies as it maintains blinding, but does not penetrate the skin or stimulate acupuncture points.

I would still disagree with the authors that this is a neutral placebo because the device still replicates the feeling of a needle regardless of the penetration into the skin or not. It is possible that superficial, skin sensation, is also a stimulus as well.

The authors conclude that there needs to be a better treatment protocol, used over multiple studies to determine efficacy, as well as determine standardized ways of measurement in relation to outcomes. They state, “the optimal acupuncture treatment protocol needs further research, including the best combination of acupoints, the number of treatment sessions, and the manipulation details.”

I agree with the authors, but also find that this continues to elude an exceptional study design. Due to the nature of acupuncture and Chinese Medicine, patients need to receive a more individualized treatment depending on signs and symptoms. The model of giving all patients the same treatment, albeit the “best acupoint protocol,” still does not maximize the potential outcomes for an acupuncture study. Due to the evidence presented by the authors here, they state that further studies need to be performed using optimal patient populations, standardized measurements, and standardized acupuncture protocols in order to clearly recommend this intervention for xerostomia due to radiation treatment in head and neck cancers.

In summary, the research articles on xerostomia that met inclusion criteria for this systematic review were, as a body, of higher quality than those that met inclusion for the review on hot flashes. This is observed in the STRICTA reviews. Information and specifics around the
type of intervention used, such as the points used, needles and manipulation of the needles was much more detailed than the articles reviewed for hot flashes. Additionally, the practitioner in these studies who are executing the intervention are detailed and trained appropriately. None of the studies included a truly diversified or mixed intervention, where treatments could be modified based on patient presentation. This is a limitation of the research, and mirrors the limitation that was observed in the review on hot flashes.

As a whole, the research presented here does tend to suggest a benefit from acupuncture for the condition of radiation induced xerostomia. Though several articles do note a lack of improvement in measured sialometry, the authors in those studies do note the limitations of this measurement. Varied measurements and outcomes from sialometry is common, and documented by the authors of this study. In self-reported data from the patients participating in the studies, there is a strong trend towards subjective improvements in oral conditions and moisture in the groups receiving acupuncture. True acupuncture tended to show greater improvements than sham treatments, and also out-performed comparator treatments such as oral care and hygiene.

Though the results compared here are not conclusive, there is a trend towards a significant benefit from acupuncture for this population. If we consider the reality that many of these patients do not have any other good options for relief of their symptoms, it merits a continued exploration of acupuncture as a possible treatment option for these patients. Acupuncture is minimally invasive, cost-effective, and can be administered safely and quickly in a hospital setting. All of these attributes makes it a viable adjunctive treatment for patients receiving radiation treatment for oral and neck cancers.
8) Conclusions

This systematic review serves the purpose of a deeper exploration into the role that acupuncture could play in the care of oncology patients experiencing hot flashes or xerostomia stemming from their treatment. The body of evidence here, as collated in this review, is mixed. There is a lack of a clear and decisive conclusion. The research that met the inclusion criteria is pockmarked with limitations, especially in the category related to hot flashes in oncology care. The actual interventions given to the patients were poorly described, and often failed to meet appropriate standards for the condition being described. The articles that did have positive outcomes were similar in their variable and flexible approach to patient treatment and intervention. As a whole, the practitioners in the study were not described adequately, and this may have also affected the outcomes negatively. If the individuals engaged in the intervention fail to meet basic qualifications, the outcomes will surely reflect in a negative way.

In the articles on xerostomia there is a stronger case for acupuncture, and this is reflected as well in the quality of the articles in this category. They certainly outperform the quality of the articles in the hot flash category. The interventions were described with more detail, and as a group the interventions were more generous in regards to frequency of the intervention being given. Though the objective saliva measurements did not consistently show improvements, the measurement itself is fraught with limitations, and the authors note that the subjective experience as reported by the patients tended to outperform standard hospital care.

This systematic review highlights the need for better quality research in the field of acupuncture. The idea that one treatment will fit all patients in a research design needs to be discussed, scrapped, and modified. Acupuncture at its root is a modality that is designed to be
modified based on patient presentation. Having research design include options for variation on
treatment may result in better outcomes.

Acupuncture has the strength of being a cost-effective intervention for oncology patients.
Despite its proven safety, it is still rarely being offered in a robust way to patients who are
undergoing oncology treatment. There is a need for greater exploration into this treatment for
these populations.
REFERENCES


