Abstracts from the Sixth IN-CAM Research Symposium: Complementary and Integrative Health Care: Methodological, Theoretical and Practical Issues

Marja J. Verhoef, University of Calgary
Heather Boon, University of Toronto

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Abstracts from the Sixth IN-CAM Research Symposium: Complementary and Integrative Health Care: Methodological, Theoretical and Practical Issues

Marja J. Verhoef and Heather Boon

Abstract

The following are abstracts of oral and poster presentations given at the sixth IN-CAM Research Symposium, Complementary and Integrative Healthcare: Methodological, Theoretical and Practical Issues, held November 19 to 21, 2010 at the Sutton Place Hotel, Vancouver, Canada. The Symposium was held in collaboration with IN-CAM partners PedCAM and HomeoNet. The abstracts are grouped under: IN-CAM, PedCAM, and HomeoNet. For more information, please visit: www.incamresearch.ca.

KEYWORDS: CAM, homeopathy, integrative health care
**IN-CAM**

**Systematic reviews of TCM trials: How does language of publication affect risk of bias?**

Denise Adams (1), Taixiang Wu (2), Sunita Vohra (2)  
(1) University of Alberta, (2) Sichuan University

**Background:** Many flaws have been identified in traditional Chinese medicine (TCM) research. Systematic reviews (SRs) base study inclusion on reported methods but the validity of this approach has not yet been formally evaluated.

**Objectives:** i) To determine the value of adding Chinese-language databases to conventional SR search strategies, and ii) to determine the importance of methodological validation of TCM randomized controlled trials (RCTs) in SRs of two health conditions, chronic fatigue syndrome (CFS) and infectious mononucleosis (mono).

**Methods:** Ten English-language and two Chinese-language databases were searched. After initial screening of titles and abstracts, potentially relevant publications were retrieved and assessed using predetermined inclusion criteria.

**Results:** Mono Search English-language databases did not yield any relevant references. Chinese-language databases identified 14 studies labelled as RCTs. Based on author interview, all were excluded - most were found to be summaries based on clinical experience. CFS Search English-language and Chinese-language databases identified 8 and 28 potentially relevant references, respectively, however, none met all inclusion criteria. Of 16 studies with author interview, only two used randomization, however, they were excluded for other reasons; five used order of enrolment, six used patient choice, and three were of another design.

**Conclusions:** Utilization of Chinese-language databases increased the number of potentially relevant references, but due to methodological flaws, the information gathered was not able to be included in the data synthesis. Trials investigating TCM must be conducted with increased methodological rigour to be of value.

**Acknowledgements:** Project support received from AHAFMR and CIHR.
The chiropractic care of patients with cancer: A systematic review of the literature

Joel Alcantara (1), Joey Alcantara (2), Junjoe Alcantara (2)
(1) International Chiropractic Pediatric Association, (2) Private Practice of Chiropractic

Background: Deaths from cancer worldwide have been projected to continue rising, with an estimated 12 million deaths by 2030. More than 30% can be prevented. Chiropractic is the largest, and most regulated CAM profession. To investigate the nature of the chiropractic care provided to this patient population, we performed a systematic review of the literature.

Methods: The following electronic databases were searched: MANTIS [1965-2010]; ICL [1984-2010]; Pubmed [1966-2010]; Medline [1965-2010]; EMBASE [1974-2010], AMED [1975-2010], CINAHL Plus [1965-2010], Alt-Health Watch [1965-2010] and PsychINFO [1965-2010]. Key words used were “cancer” and “neoplasm” in Boolean combination with “chiropractic” along with related words when appropriate. Eligibility criteria was: (1) the study was a primary investigation/report published in peer-reviewed English language journals; and (2) part or all of the study population involved patients with cancer.

Results: Our systematic review revealed 21 commentaries, 2 survey studies, 2 literature reviews, 2 case series and 60 case reports. The vast majority are diagnostic in nature and confirm risk factors for cancer patients such as a history of cancer, and failure to respond to conservative care and continued clinical deterioration.

Conclusion: We recommend future research in this field to characterize the nature of the supportive care provided by chiropractors to reducing pain and suffering and improve overall quality of life of cancer patients.

Acknowledgements: Project support received from The International Chiropractic Pediatric Association.

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A systematic review of the literature on the chiropractic care patients with Autism Spectrum Disorder

Joel Alcantara (1), Joey Alcantara (2), Junjoe Alcantara (2)
(1) International Chiropractic Pediatric Association, (2) Private Practice of Chiropractic

Background: Autism and its related disorders diminish the quality of life of the affected individual and their families and represent a great burden to society. Since no pharmacological treatments are effective for the core symptoms of Autism Spectrum Disorder (ASD), alternative therapies have become a viable care approach.

Objectives: To provide context for the chiropractic care of children with ASD.

Methods: A systematic review of the literature was performed. We examined the following databases: MANTIS [1965-2010]; Pubmed [1966-2010]; Index to Chiropractic Literature [1984-2010]; EMBASE [1974-2010]; AMED [1967-2010]; CINAHL [1964-2010]; Alt-Health Watch [1965-2010] and PsychINFO [1965-2010]. Inclusion criteria were peer-reviewed manuscripts addressing the chiropractic care of children with ASD in the English language. Chiropractic journals were also hand-searched for the last five years for possible relevant materials as well as consulting experts and the grey literature.

Results: Our systematic review of the literature revealed a total of 10 articles consisting of 3 case reports, five commentaries, one cohort study and one randomized comparison trial.

Conclusion: Our literature review demonstrated the lack of research (in both quantity and quality) on the chiropractic care of children. In the interest of evidence-based practice, we encourage further research in this field.

Acknowledgements: Project support received from The International Chiropractic Pediatric Association.
CAM decision making during prostate cancer: When "Time is on my Side"

Lynda Balneaves (1), Jennifer Bell (1), Tracy Truant (2), Joyce Davison (3) (1) University of British Columbia, (2) BC Cancer Agency, (3) University of Saskatchewan

Background: Between 18-72% of men with prostate cancer use complementary and alternative medicine (CAM). Although research has uncovered the motivations behind men’s CAM use, little is known about their decision-making process. Such knowledge is essential to develop CAM education and decision support interventions.

Objectives: The study purpose was to 1) explore how men with prostate cancer make decisions about CAM and 2) develop a conceptual model of the decision-making process.

Methods: A purposeful sample of 20 men was interviewed about their CAM decisions, factors associated with the decision-making process and information sources used. Grounded theory and constant comparison were used in the analysis.

Results: The core category was “Time is on my Side”, in which men perceived themselves to have the time to consider treatment alternatives and reflect on their pre-disposing beliefs about CAM. Men approached CAM decisions from two perspectives: “Casting a wide net” and “Focusing one’s treatment approach”. Men who casted a wide net had limited past CAM experience and moved through a whittling down process of seeking/evaluating information and weighing risks versus benefits. Focusing one’s treatment approach was seen in men with prior CAM use, an established relationship with a CAM practitioner, and a strong desire for control. These men engaged in a validating process of using CAM and monitoring its effect.

Conclusion: The conceptual model provides guidance regarding the level and type of CAM information and decision support required by men with prostate cancer. The implications for education and decision support interventions will be discussed briefly.

Acknowledgements: Project support received from CIHR and the Canadian Breast Cancer Research Alliance.
Women with breast cancer’s Natural Health Product information and decision support needs related to managing menopausal symptoms

Alison Brazier (1), Lynda Balneaves (1), Leah Lambert (1), Dugald Seely (2), Members of MyChoices Research Team (3)
(1) University of British Columbia, (2) The Canadian College of Naturopathic Medicine, (3) The CAMEO Research Program

Background: More than half of breast cancer survivors experience menopausal symptoms following cancer treatment. Many women look toward non-hormonal therapies to manage symptoms, with natural health products (NHPs) being among the most commonly used.

Objectives: In phase one of this three-phase study, which will develop and evaluate a NHP decision aid for breast cancer survivors experiencing menopausal symptoms, a needs assessment was conducted. The purpose was to understand the types of therapies women consider to manage symptoms, and their need for information and support when making treatment decisions.

Methods: Several focus groups were conducted with breast cancer survivors recruited through two Canadian cancer agencies. Focus groups were 90 minutes, digitally recorded, and transcribed verbatim. Women were asked about how they make treatment decisions, challenges they experienced, and the support and resources they access and require. Data was analyzed using inductive thematic analysis.

Results: Findings highlight a high degree of distress for women due to challenges in finding safe and effective treatment options. Women consider many treatments including pharmaceuticals, NHPs, other CAM therapies, and draw on multiple sources of information (e.g., health professionals, the Internet, family and friends, other survivors). Women identify a lack of accessible and reliable information to inform their decisions, and desire condensed, summarized, and credible information about the most promising and safe treatment options. Women provided specific feedback regarding the design of the decision aid. Conclusion: Findings will inform the content and structure of the NHP decision aid. An overview of the decision aid will be presented.

Acknowledgements: Project support received from the Canadian Breast Cancer Research Alliance.
The effect of therapeutic massage on muscle parameters in fibromyalgia patients: A pilot study

Judah Bunin (1), Wayne Albert (2), Lisa Ivany (3)
(1) Fredericton Naturopathic Clinic, (2) University of New Brunswick, (3) Atlantic College of Therapeutic Massage

Background: There is little objective evidence to support the widely held belief that massage increases circulation to the muscles. NIRS technology provides a simple, non-invasive means of assessing muscle blood volume and oxygenation changes following massage treatment.

Objectives: To provide objective information about the fundamental assumption that massage therapy increases blood flow to the muscles, and to further our understanding about the mechanisms by which massage may provide therapeutic relief for fibromyalgia.

Methods: Six fibromyalgia and three control subjects each received a series of 6 weekly massage treatments. During alternate sessions, NIRS and EMG sensors were applied to the belly of the trapezius muscle, and Fibromyalgia Impact Questionnaires were completed. Changes in blood flow, muscle oxygenation, and EMG responses were tracked by treatment technique and the data were examined for correlations between subjective changes and objective measurements of muscle parameters.

Results: Although full statistical analysis has yet to be completed, it appears that initially fibromyalgia subjects responded to massage with a decrease in blood flow to the trapezius muscle, while healthy controls had little change in this regard. However, by the end of the six treatments, this difference in response between groups seems to have disappeared. Conclusion: Early analysis suggests that massage treatment may affect muscle parameters differently in subjects with fibromyalgia compared to healthy controls. Furthermore, this difference seems to disappear after a course of six weekly massage therapy sessions.

Acknowledgements: Project support received from the Massage Therapy Research Foundation.
The cultural worldview of allopathic and naturopathic physicians

Cullen Clark (1)
(1) University of Alabama at Birmingham

**Background:** The epistemic and ontological structure of worldview influences every aspect of culture, including medicine. To understand differences between biomedicine and complementary/alternative medicine (CAM), it is essential to explore the worldview of practitioners.

**Objectives:** To identify components of worldview among primary-care allopathic and licensed naturopathic physicians, and examine their influence upon support for various types of CAM.

**Methods:** Licensed naturopaths and primary-care allopaths were surveyed in states where both are licensed to practice. Likert items probed topics ranging from medicine to metaphysics to perceived efficacy of various therapies. Cluster analysis identified items separating allopaths and naturopaths. Principal components analysis (PCA) distilled these into independent variables used in regression models exploring influence upon perceived efficacy of five types of CAM. Three naturopaths and three allopaths were interviewed about the findings.

**Results:** Sample included 550 allopaths, 399 naturopaths. Cluster analysis identified 26 items ($\alpha = .907$) dividing respondents into two clusters; one 95.1 percent naturopaths, the other 95.7 percent allopaths. PCA extracted five components – spirituality, deep ecology, nature of medicine, critique of science, and diagnosis and treatment. Regressions revealed each exercised differing degrees of influence depending on physician type and CAM domain. For every CAM type except energy medicine, worldview explained more variance for allopaths. The physician panel agreed components reflected aspects of worldview upon which allopaths and naturopaths often differ, and worldview may have more influence among allopaths because they lack clinical CAM experience.

**Conclusion:** Worldview counts. Its influence appears to be contextual. Components exercise differing degrees of influence, depending on type of physician and CAM domain – key information for building an integrated medical system.

**Acknowledgements:** No acknowledgements identified.
Ethnography and theatricality: Trialling a novel methodology for the holistic study of complex interventions in CAM

Sarah Croke (1)
(1) University of Leeds

**Background:** A holistic methodology for CAM research is lacking. The clear parallel between the concept of ‘theatre’ as a global experience, where every aspect is a vital part of the whole event, and complex healthcare interventions, supports the proposal of theatricality (a mode of perception) with ethnography to capture, compare and contextualise the realities of CAM practice, from ‘staging’ to ‘outcomes’, in geographically/culturally diverse settings.

**Objectives:** 1) To document and compare the different ‘staging’ methods employed by practitioners and the factors underpinning them; 2) to record and compare the impact of ‘staging’ methods on the practice and experience of CAM; and 3) to trial the use of ‘theatricality’ as an adjunct to ethnography in the holistic study of complex interventions.

**Methods:** Observations will use theatricality as a guiding methodology, enabling practice composition to be holistically appraised. Ethnographic interviews with practitioners and patients will explore the observational data and determine the impact of contextual factors on treatment delivery and outcomes.

**Results:** A pilot study is due to run during October 2010. The effectiveness of theatricality as an adjunct to ethnography for capturing data on complex interventions will be demonstrated and the effects of staging methods on the practice and experience of CAM will be explored.

**Conclusion:** Trialling theatricality in this study may facilitate appreciation and use of this concept as a healthcare research methodology. The validity of the placebo concept in CAM practice and research can be questioned if contextual factors are found to act primarily via their effect on the practitioner.

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Agree to disagree: The two versions of medical acupuncture in western healthcare

Ellen Crumley (1)
(1) University of Alberta

**Background:** Traditional Chinese Medicine acupuncture (TCMa) gained widespread attention in 1971 when U.S.–Sino relations were re-ignited and western physicians visited China to study acupuncture. These events prompted the rise of medical acupuncture (MA) which is practiced by western healthcare professionals like physicians and physiotherapists. Unexpectedly, two versions of MA have developed; one is rooted in western medical science (MS-MA) and the other blends medical science and TCMa (TCMa-MA).

**Objective:** To examine the contestation surrounding the two versions of MA and its impact upon MA’s acceptance and diffusion in mainstream western healthcare.

**Methods:** Textual analysis of 10 textbooks and 173 articles from MEDLINE and EMBASE.

**Results:** The two versions of MA incorporate different practices and philosophies. TCMa-MA is grounded in Chinese philosophy and theory; practitioners combine TCM and western diagnostic systems and therapeutic approaches. TCMa-MA also incorporates a variety of practices (e.g., needling, herbs, TCM diagnosis) while MS-MA focuses more upon needling. The medical science version emphasizes scientific explanations of acupuncture (e.g., neuronal, anatomical, musculoskeletal) and the conduct of high-level western research evidence (e.g., randomized controlled trials). Nevertheless, MA supporters cannot agree upon which version should be practiced in western healthcare.

**Conclusion:** Investigating MA increases understanding of how some complementary and alternative (CAM) practices can be integrated into western healthcare. Although “acupuncture” is popular in CAM surveys, contestation about the two versions has hindered MA’s incorporation into western healthcare. My research examines why MA has not become part of mainstream healthcare even though it is endorsed by western professionals.

**Acknowledgements:** Project support received from SSHRC.
Cancer survivors with lymphedema: Perceptions of using traditional acupuncture as an adjunct to usual care

Beverley de Valois (1), Anthea Asprey (2), Teresa Young (1)
(1) Lynda Jackson Macmillan Centre, (2) University of Exeter

Background: Within a mixed-methods design to investigate using traditional acupuncture (TA) to promote wellbeing and improve quality of life in cancer survivors with lymphoedema, this qualitative study explored participants’ perceptions of TA treatment.

Objectives: To gather qualitative data about participants’ experiences of TA treatment as an adjunct to usual care for lymphedema.

Methods: 32 lymphedema patients, who received up to 13 individualised TA treatments (which did not aim to treat the lymphedema), were invited to participate in focus groups to discuss their experiences. Transcripts were analysed using a thematic framework approach, coded iteratively using NVivo, and checked by a second researcher to ensure systematic analysis.

Results: 6 head & neck and 17 breast cancer survivors (n=23) participated in 6 focus groups. Lymphedema, the “last straw” after cancer treatment, could leave participants disfigured, disabled and vulnerable. Despite initial scepticism, participants responded positively to the opportunity to try TA. They reported short-term and longer-term benefits on a range of physical and emotional conditions, including some lymphedema-related changes. Participants appreciated the therapeutic relationship and being treated as a “whole person”. Many felt more positive and confident, more in control of their lives, and better able to tolerate having lymphedema.

Conclusion: Overall, participants found TA acceptable. Many experienced substantial and positive impacts on various aspects of physical and emotional health, and some reported improvements in their attitude towards having lymphoedema. Data suggest that TA may be a useful adjunct to usual care, offering cancer survivors a non-pharmacological option to help manage a chronic condition.

Acknowledgements: Project support received from NIH.
From research into practice: Do breast cancer patients using an ear acupuncture service to manage menopausal side-effects of adjuvant hormonal treatment do as well as those participating in a research study?

Beverley de Valois (1), Teresa Young (1), E J Maher (1)
(1) Lynda Jackson Macmillan Centre

Background: Research participants often have better outcomes than patients receiving the same treatment in standard care settings. After introducing an ear acupuncture service to treat menopausal side-effects of adjuvant hormonal treatment (AHT) for early breast cancer, we aimed to test this by comparing the outcomes with those of our previous research study.

Objectives: To test the hypothesis that service users report poorer outcomes than research participants.

Methods: Ninety-three women self-reporting ≥4 hot flushes (HF)/day and receiving AHT had eight weekly treatments using the National Acupuncture Detoxification Association (NADA) ear acupuncture protocol, administered by trained non-acupuncturists. Inclusion criteria and outcome measures repeated those in our previous NADA study. We compared data, compliance with treatment and questionnaire completion with that from the research study.

Results: Nine patients were recruited in contravention of the inclusion criteria (<4 HF/day), and 17 did not return end of treatment (EOT) data. Analysis of 67 patients with EOT data shows a 43.9% (95% CI 35.3-51.3) reduction in HF frequency at EOT. This is not significantly different from the reduction demonstrated during the research project, which was 35.9% (95% CI 25.4-45.4). Five service users (6%) did not complete the course of 8 treatments, compared with 2 research participants (4%). 26.9% of the EOT and follow-up questionnaires were missing compared to 10.1% in the research project. Conclusion: Service users appear to be significantly less compliant in completing paperwork. For those returning data, there is no significant difference in response rate compared to that reported in the research study.

Acknowledgements: Project support received from the Lynda Jackson Macmillan Centre.
How involving patients in research design shaped a study for using traditional acupuncture for cancer survivors with secondary lymphoedema

Beverley de Valois (1), Teresa Young (1)
(1) Lynda Jackson Macmillan Centre

Background: The UK’s National Institute of Health Research (NIHR) encourages active involvement of patients and public in health care research, to ensure that research focuses on what is important to service users, and is relevant and acceptable to them. Patient involvement was used to design an exploratory study into using traditional acupuncture (TA) to improve wellbeing for breast (BC) and head and neck cancer (HNC) patients with secondary lymphoedema.

Objectives: To involve patients and clinicians in designing a clinical study that was acceptable and relevant to patient needs.

Methods: Eight focus groups were conducted with BC (n=23) and HNC (n=8) patients and their clinicians (n=8). Participants considered acceptability of TA, identified troublesome symptoms, and discussed potential obstacles and facilitating features of an acupuncture service.

Results: Participants agreed TA was an acceptable adjunct to usual care for lymphoedema, providing that needling was avoided in the affected area (including the entire quadrant for BC participants). Diverse and individual symptoms resulted in an individualised, rather than a standardised, protocol for acupuncture treatment. Participants specified preferences for treatment by the same practitioner, flexible appointment times, and “time off” to accommodate personal events. Patients’ and clinicians’ opinions about duration of treatment differed, leading to a design to test the feasibility of longer-term treatment protocols.

Conclusion: Patient and clinician inputs actively shaped the design of the clinical phase of this study, helping to ensure it was acceptable and relevant to their requirements. This contributed to the study’s success, especially regarding participants’ compliance to study protocols.

Acknowledgements: Project support received from NIH.
Using traditional acupuncture to promote wellbeing and improve quality of life in cancer survivors with lymphedema

Beverley de Valois (1), Teresa Young (1), Elaine Melsome (2), Jane Maher (1)
(1) Lynda Jackson Macmillan Centre, (2) Mount Vernon Lymphoedema Service

Background: Using acupuncture in lymphedema management is controversial, with assumptions that it will exacerbate the condition and introduce infection. This innovative study explores using Traditional Acupuncture (TA) as an adjunct to usual care, testing acceptability and measuring impact on wellbeing and quality of life.

Objectives: To assess whether TA can improve wellbeing in cancer survivors with lymphedema, to identify troublesome symptoms, and to assess safety.

Methods: An exploratory single-arm clinical study included breast (BC) and head and neck cancer (HNC) with mild to moderate uncomplicated lymphedema for ≥3 months, ≥3 months post active cancer treatment, no active cancer disease, treated by specialist lymphedema clinic. Participants received 7 individualised TA treatments (S1), with the option of 6 additional treatments (S2). The Measure Your Medical Outcome Profile (MYMOP) was administered for each series.

Results: Of 35 patients recruited, 30 completed S1 and S2, 3 completed S1, 2 were lost to the study. The MYMOP profile change score for BC participants for S1 was 1.28 (sd=0.93) points improvement on a 7-point scale, p<.0001 (n=25) where improvement is a positive change; and for S2 was 1.41 (sd=0.94), p<.0001 (n=24). For HNC participants, MYMOP profile change scores for S1 were 2.29 (sd=0.62) points improvement, p<.0001 (n=7); and for S2 was 0.94 (sd=0.95) p=0.06 (n=6). Patients specified a variety of symptoms that they found troublesome. No adverse affects were observed or reported.

Conclusion: Data indicate that TA can improve a variety of symptoms experienced by cancer survivors with lymphedema, and appears to be a safe intervention.

Acknowledgements: Project support received from NIH.
A foot in both worlds: Acupuncture, education, and identity at a university of natural medicine in the United States

Hannah Flesch (1)
(1) McMaster University

**Background:** Despite the prominence of complementary and alternative medicine (CAM) in public and policy debates, the socialization of CAM students and the implications of this process for the identity of CAM remains relatively unexplored.

**Objectives:** The study of institutions of CAM education offers a unique window onto broader issues of the shifting identity and future of CAM in the United States. By focusing upon curriculum change and the process of learning among first year students in the Master of Science in Acupuncture and Oriental Medicine (AOM) program, I explore the ways in which increasing emphasis upon integration with biomedical models of education, practice, and research influences the AOM curriculum, the professional values inculcated within first year AOM students, their sense of professional identity and position within the US medical landscape, as well as the identity of AOM itself. In addition, this paper elucidates how the interests, goals, and decisions of first year students shape and influence the curriculum and the identity of AOM. This paper will explore these ideas as well as the theoretical and practical issues surrounding ethnographic research at a school of CAM, with emphasis upon the value and limitations of such methods for advancing our knowledge of CAM education, professionalization, and research.

**Methods:** Ethnographic research was conducted between September 2006 – August 2007 at a large, multidisciplinary institution of natural medicine in the United States. The primary means of data collection occurred through participant-observation of classroom lecturers, labs, and clinical training sessions, interviews with students and faculty; and student-led focus groups.

**Results and Conclusion:** Far from passive transmitters of CAM knowledge and skills, schools of CAM play a pivotal role in shaping the regulatory landscape as well as health care in the United States. A longitudinal and comparative approach to the study of CAM institutions is necessary to achieve a more complete understanding of this role as well as the process by which students become professional practitioners of CAM.

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Professional status within an interprofessional context: A view of massage therapy

Cathy Fournier (1), Scott Reeves (2)
(1) University of Toronto, (2) The Wilson Center

Background: Massage therapy is one of the fastest growing complementary and alternative medicine (CAM) modalities in North America. It has now gained acceptance in the general public as a treatment for musculoskeletal pain and the management of other chronic conditions. There is also a growing body of evidence for the efficacy of massage therapy in managing a number of conditions considered a strain on the health care system. Massage Therapists are currently regulated under the Regulated Health Professions Act in Ontario – the same Act governing physicians, nurses and physiotherapists. However, massage therapists continue to have lower professional status when compared to many of these other groups. While interprofessional collaboration is vital for the delivery of patient/client care, massage therapists can often be excluded from interprofessional referrals and dialogue about care among practitioners. This can compromise the nature of their interprofessional relationships, impede professional growth for massage therapy and undermine benefit for patients/clients.

Objectives: To explore: 1. perceptions of professional status of massage therapists within an interprofessional context; and 2. experiences of a range of professional, organizational and educational factors to help understand how the perceived status affects interprofessional relationships.

Methods: This study employs an exploratory qualitative case study approach based on in-depth interviews with a range of health care professionals working in a hospital setting. As the literature currently provides little empirical information about the nature of the issues related to perceptions and experiences of massage therapists related to professional status, an exploratory qualitative research design is needed to begin to generate an initial understanding into this area. Data will be analyzed using inductive thematic coding to generate key themes. The presentation initially describes emergent themes before discussing them in relation to the wider interprofessional empirical and theoretical literature. Over time, it is anticipated that this study will contribute to our understanding of how the professional status of massage therapists affects the nature of their collaborative work.

Acknowledgements: Project support was received from the Holistic Health Research Foundation of Canada.
Fish derived omega-3 fatty acids for lung cancer: A systematic review

Heidi Fritz (1), Deborah Kennedy (1, 2), Rochelle Fernandez (1,2), Dugald Seely (1)
(1) Canadian College of Naturopathic Medicine, (2) University of Toronto

Background: Fish oil/omega-3 fatty acid supplements are among the most common natural health products (NHPs) used by cancer patients, but there is no synthesis of current knowledge for use in lung cancer.

Objectives: Systematic review of the safety and efficacy of fish oil/eicosapentanoic acid (EPA) for the treatment and prevention of lung cancer.

Methods: We searched six electronic databases from inception to May 2010 for clinical, observational, and preclinical evidence pertaining to the safety and efficacy of fish oil/EPA for lung cancer.

Results: Of 636 records, 50 studies were included for full review and analysis. Six RCTs and two phase II trials were included for the treatment of cachexia in lung cancer patients, and one phase II trial was included for treatment of lung cancer. Eleven observational and 30 preclinical studies were included. Modest clinical benefit from use of fish oil and/or EPA was seen on parameters associated with cachexia, notably weight loss, appetite, and physical function. There were also modest improvements seen in quality of life. One study found significant benefit on survival with high dose fish oil. The recommended dose is ≥ 2g EPA per day. There were no serious adverse events associated with use of fish oil in the studies reviewed.

Conclusion: Fish oil/EPA appears safe and may be effective in the treatment of cachexia and related symptoms. Use of EPA as part of a multifaceted approach to the treatment of cachexia may be advantageous in clinical settings.

Acknowledgements: Project support received from CIHR.
Green tea and lung cancer: A systematic review

Heidi Fritz (1), Deborah Kennedy (1, 2), Rochelle Fernandez (1,2), Dugald Seely (1)
(1) Canadian College of Naturopathic Medicine, (2) University of Toronto

**Background:** Green tea from Camillia sinensis is a beverage widely used by lung cancer patients and the public at large for its purported anticancer properties.

**Objectives:** Systematic review of the safety and efficacy of green tea for the treatment and prevention of lung cancer.

**Methods:** We searched Pubmed, EMBASE, CINAHL, Cochrane, AltHealth Watch, and the National Library of Science and Technology, from inception until February 2010, for human, observational, and preclinical evidence pertaining to the safety and efficacy of green tea for lung cancer.

**Results:** Of 1056 records screened, 64 studies met inclusion criteria. Of these, two were Phase I trials, three were reports of one surrogate study, 14 were observational studies, and 47 were preclinical studies. The maximum tolerated dose ranged from 3 to 4.2 g/m² per day, and this was better tolerated in divided doses. Seven of 14 observational studies showed a significant protective effect associated with higher levels of green tea intake.

**Conclusion:** There is insufficient evidence around the efficacy of green tea for the treatment and prevention of lung cancer. Green tea appears to be safe at doses purported to have anticancer activity, up to 1500 mL per day. Further human intervention trials are necessary to explore the potential benefits of green tea or extracts of this natural health product for use in lung cancer treatment and prevention.

**Acknowledgements:** Project support received from CIHR.
Polysaccharide K (PSK) and lung cancer: A systematic review

Heidi Fritz (1), Deborah Kennedy (1, 2), Rochelle Fernandez (1,2), Dugald Seely (1)
(1) Canadian College of Naturopathic Medicine, (2) University of Toronto

Background: Polysaccharide K (PSK) is a protein-bound polysaccharide isolated from the mushroom Coriolus versicolor, and has been used in Japan for over thirty years as adjunctive cancer therapy. PSK has been purported to improve the immunological antitumor response, however, no synthesis of current knowledge exists for use of PSK in lung cancer.


Methods: We searched six electronic databases from inception to October 2009 for clinical, observational, and preclinical evidence pertaining to the safety and efficacy of PSK for lung cancer. Because PSK has a long tradition of use in Japan, we included both Japanese and English language reports of controlled human trials.

Results: Of 186 records, 39 were included for full review and analysis. Thirteen were English or Japanese language reports of human clinical trials, and 28 were preclinical studies. There was evidence that use of PSK as long term adjuvant therapy in lung cancer patients who had undergone radiation therapy may improve clinical outcomes including survival rates at two and five years. There was also evidence suggesting that PSK may reduce toxicities associated with chemotherapy, immunosuppression in particular, and increase quality of life. The recommended dose based on human trials is 3g PSK per day.

Conclusion: PSK appears safe and may be effective for the secondary prevention of lung cancer. PSK may reduce chemotherapy induced toxicities. Further research is needed in North American populations.

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CAM-related content of Canadian postgraduate medical programs

Isabelle Gaboury (1), Marianne Xhignesse (2), Marja Verhoef (1)
(1) University of Calgary, (2) Université de Sherbrooke

Background: Research has reported a continued interest of the medical community to expand its knowledge of Complementary and Alternative Medicine (CAM). However, existing surveys show limited CAM content in the curriculum at the undergraduate level of medical schools, as well as limited knowledge among medical students. The CAM content of post-graduate programs is not well documented.

Objectives: To assess CAM content of residency programs and perceived level of preparedness to answer patients’ questions about CAM.

Methods: Online survey of residents enrolled in programs at the University of Calgary, the Université de Sherbrooke, and University of Ottawa Faculty of Medicine.

Results: Among the 405 respondents (response rate 20%), 42% confirmed being exposed via lectures or seminars to some CAM content during their training (among a list of 9 CAM modalities). Only 21% reported that their training was adequate to meet their patients’ expectations on CAM topics and felt unprepared to answer patients’ questions (median 2 on a 10-point scale). 172 residents (43%) were asked questions about CAM at least every week. 78% thought it was their role to answer their patients’ questions related to CAM and more than half thought it was important to increase the CAM-related content of the residency program.

Conclusion: Medical residents are insufficiently prepared to guide their patients regarding CAM related topics. This study indicates a need to increase CAM-related content in residency programs since residents reported being frequently confronted with CAM questions. Surveys of other Canadian faculties to confirm these results are ongoing.

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Research perceptions and utilization among massage therapists in Saskatchewan, Canada

Donelda Gowan-Moody (1), Anne Leis (1), Kalyani Premkumar (1), Sylvia Abonyi (1)
(1) University of Saskatchewan

Background: To foster improved client care and the continued professionalization of Massage Therapy, it is important that MT practitioners’ research utilization is more clearly understood.

Objectives: To: 1. describe MT’s perceptions of research and their appraised self-efficacy in research literacy and capacity; 2. better understand the nature of research utilization; and 3. identify what characteristics are associated with research utilization.

Methods: Using a sequential explanatory mixed methods design, the study was conducted in two phases. In the first phase, all (815) registered members of the Massage Therapist Association of Saskatchewan (MTAS) were invited to participate in a mail-out survey. In the second phase, semi-structured qualitative interviews using a critical incident framework explored in more in depth the nature of practitioners’ use of research. Univariate and logistic regression analysis were conducted using SPSS.

Results: A total of 333 questionnaires were completed and returned for a 40.9% response rate. While overall perceptions of research were positive, self-efficacy in research literacy and capacity was low. Referring to PubMed, referring to peer-reviewed journals, believing that MT practice should be based on research, and working more than 20 hours per week were all predictive of research utilization. Case study participants’ descriptions of critical events revealed key issues of access, assumptions, and impact on care.

Conclusion: It appears that while registered members of the MTAS perceive research positively, there is a gap between what is known from research and what is utilized in practice. Support for students and practitioners is needed from schools, the Association, and the research community to aid in the diffusion of research information.

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The association between acupuncture, acupuncture beliefs and smoking cessation in a Baltimore homeless shelter

Cynthia Johnson (1), Payam Sheikhattari (1), Fernando Wagner (1), Fernando Wagner (2), Lixing Lao (3)
(1) Morgan State University, (2) Peoples’ Community Health Center, (3) University of Maryland

Background: Cigarette smoking is the first preventable cause of death in the U.S. Smoking cessation programs have not been equally effective for under-served populations, particularly those with special needs. Acupuncture has been used to treat various addictions. However, studies have been inconclusive about the benefits of acupuncture for smoking cessation.

Objectives: To examine the effectiveness of acupuncture among residents living in a homeless shelter, and the role of beliefs in acupuncture regarding smoking cessation.

Methods: Patients received auricular acupuncture according to the National Acupuncture Detoxification Association protocol 3 times per week for 4 weeks. Baseline and exit measurements document participants’ beliefs about acupuncture, nicotine dependence, patient practitioner interaction, and sessions attended. Multivariate analyses are presented.

Results: Eighty-seven patients were enrolled. Only 35 (40%) patients completed the protocol; 47% attended 6 or more sessions. Forty-three percent had no preexisting acupuncture expectation, 28% had low expectations, and 30%, high. Only 2 patients quit smoking. However, 60% decreased in nicotine dependence scores. Contrary to prior research, no associations were found between beliefs and number of sessions attended, reduction in nicotine dependence or cessation in multivariate models.

Conclusion: Acupuncture may help some high risk smokers quitting tobacco. Additional research is needed to better understand the combined effects of expectations and acupuncture. Further research may shed light on the mechanisms linking characteristics of those who can benefit from this CAM modality for smoking cessation.

Acknowledgements: Project support was received from NCCAM.
Developing a clinical assessment tool to promote the implication of Western Traditional Herbalism practitioners in NHP research

Marie Jutras (1,2), Sara Ahmed (3), Nadine Methot (4), Marie-Christine Vallières (1), Geneviève Siros (1), Marie Provost (1,2), Sunita Vohra (5), Mark Ware (3), Pierre Haddad (1, 4)  
(1) Guilde des herboristes du Québec, (2) La Clef des Champs, (3) McGill University, (4) Université de Montréal, (5) University of Alberta

Background: During discussions between herbalists and academic researchers on the role of herbalists in Canadian NHP research, the need to develop adequate research tools to document the practice and intervention of Traditional Western Herbalism (TWH) became evident.

Objectives: The present project therefore aimed to develop a “universal” clinical assessment form to document the practice of TWH; respecting the wholistic approach of TWH yet being acceptable to conventional medicine, essential conditions for clinical research in the realm of the TWH paradigm. Representatives of the Canadian Council of Herbalist Associations, including Ontario, Quebec and British Columbia member groups, as well as basic and clinical academic researchers composed the research team.

Methods: A form was developed based on assessment tools already used by certain practicing herbalists and was modeled upon the “Subjective, Objective, Assessment, Plan” tool of medical physicians. Intervention, Evaluation and Revision were added by herbalists as other important components. The resulting SOAPIER grid, with accompanying patient health questionnaire, reached consensus after several rounds of consultation and a field test with a limited number of practitioners. The study involved testing the tools on 3-4 patients in a herbalist’s regular practice over a minimum period of one month.

Results: A total number of 13 Canadian herbalists volunteered and 9 completed the study. Study results were compiled from evaluation forms and analyzed using standard outcomes research approaches.

Conclusion: Essentially, the tools were found too cumbersome to integrate in regular practice, but found promising for research purposes. The research team proposed several recommendations to improve the tools and future studies.

Acknowledgements: Project support received from the IN-CAM Pilot Research Grant 2008.
**CAM practitioners' perceptions and use of “evidence”**

Ania Kania (1), Antony Porcino (1), Marja Verhoef (1)
(1) University of Calgary

**Background:** CAM professions continue to promote research literacy and evidence-informed practice. Yet little is known about what “evidence” is to CAM practitioners.

**Objectives:** This study explores and describes what evidence means to CAM practitioners in context of their practice.

**Methods:** Using convenience sampling, fifteen massage therapists, five naturopaths, and eight yoga teachers were recruited in Alberta and British Columbia, Canada. Transcripts of the semi-structured interviews were analyzed using a qualitative descriptive approach. Interviews continued until no new themes emerged.

**Results:** Participants described evidence using concepts such as objective and measurable. Yet, in the context of their practice, evidence was a much broader concept, which included personal experience, established authorities and scientific research. Practitioners identified diverse factors that establish a source as evidence, such as, congruence with other sources, trust of the source, and access to the source. The perception and use of evidence is context specific. For example, treatment decisions are based on personal experience, however, research is used in communication with other health care providers. Interestingly, many reflected that the interviews led them to think and talk about evidence in ways many had not done before.

**Conclusion:** For CAM practitioners, evidence comes from various sources and is valued and used in many different ways. There appears to be a gap between having a sense of what evidence should be and how evidence is used in practice. This finding will assist the development of more specific training and education such that CAM practices are evidence-informed.

**Acknowledgements:** Project support received from the IN-CAM Pilot Research Grant 2008.
Objective assessment of an ionic footbath (IonCleanse®): Measuring its ability to remove toxic elements through the feet

Deborah Kennedy (1), Kieran Cooley (1), Thomas Einarson (2), Dugald Seely (1)
(1) Canadian College of Naturopathic Medicine, (2) University of Toronto

Background: Claims that ionic footbaths eliminate toxins including heavy metals from the body have not been rigorously evaluated.

Objectives: In this proof-of-principle study, we sought to measure the release of non-toxic and toxic elements from ionic footbaths into distilled and tap water without feet, then determine footbath’s ability to remove toxic elements through the feet of healthy participants.

Methods: Water samples were collected and analyzed (CanAlt Health Laboratories) following 30-minute ionic footbath (IonCleanse SOLO®) sessions without feet using both distilled (n=1) and tapwater (n=6), and following four ionic footbaths using tap water (once/week for 4 weeks) in six healthy participants. Element content/sample was summed in µg/L. Elements were analyzed descriptively; Mann-Whitney U test compared pre-post footbath levels and Kruskal-Wallis tests contrasted groups (distilled water, tap water/no feet and tap water with participants’ feet).

Results: Total element content of distilled water increased 121% (137,610 → 304,554 µg/L) and of tap water 107% (137,772 → 284,851 µg/L; p=0.009). Increases comprised predominantly chromium, iron and nickel (common components in the machine’s metal array). The percentage change in toxic elements was greater in distilled (65.4%) than tap water (25.7%). Testing participants, element levels increased 96.4% above baseline (p<0.0001), also associated mainly with chromium, iron and nickel. Total toxic elements increased 17.6% from baseline consistent with the release of toxic elements from running the machine with no feet.

Conclusion: The footbath tested causes a release of certain elements into the ambient water. However, contrary to claims made for the machine, there does not appear to be any specific induction of toxic element release through the feet when running the machine according to specifications.

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Efficacy of acupuncture treatment of sexual dysfunctioning secondary to antidepressants

Baljit Khamba (1), Millie Lytle (1), Monica Vermani (1), Martin Katzman (1) (1) S.T.A.R.T Clinic for Mood and Anxiety Disorders

Background: Antidepressants including Specific Serotonin Reuptake Inhibitors (SSRI) and Specific Serotonin Noradrenaline Reuptake Inhibitors (SNRI) are known to cause secondary sexual dysfunction. Sexual dysfunction related to antidepressants, although far from rare, remains highly unrecognized. The prevalence of antidepressants induced sexual dysfunction has been reported to be as high as 50%, 70%, or even 90%. Emerging research is establishing that acupuncture is an effective treatment modality for sexual dysfunction including impotence, loss of libido, and inability to orgasm.

Objectives: The goal of the study is to conduct an open label trial examining the effectiveness of acupuncture for psychiatric patients with known sexual dysfunction secondary to antidepressants.

Methods: This is an investigational, open label study using a fixed acupuncture protocol of points commonly used to treat sexual dysfunction in clinical practice. One-inch 34 gauge disposable needles were inserted and left for a total of 15 minutes at 9 common acupuncture points for 12 sessions. Five of the points were tonified at the 5 and 10 minute mark; Kidney 3 (bilateral), Governing Vessel 4, Urinary Bladder 23 (bilateral) while the neutral method was used with Heart 7 (bilateral) and Pericardium 6 (bilateral). 20 psychiatric patients with known sexual dysfunction secondary to antidepressants. SFQ, DISF-SR, DSFI, ASEX and VAS have been used to establish change in sexual dysfunction over the course of 12 sessions.

Results: We continue to be at the data-collection stage of the study, however early data will provide preliminary results for further cases in this series.

Conclusion: Acupuncture is a possible treatment for anti-depressant induced sexual dysfunction.

Acknowledgements: Project support received from CAMH.
Study for research trends on radioprotective effects of herbs

Soojin Lee (1)
(1) Sangji University

Background: Cancer is already a well-recognized main cause of mortality and the incidence of cancer is increasing steadily. Because conventional treatment modalities for cancer accompanies severe side effects, traditional medicine have been considered as alternatives to reduce the adverse effects and the use have continued to rise in cancer therapy.

Objectives: This study aims to summarize and make a reference of radioprotective effects of herbs worldwide.

Methods: This review surveyed all papers of radioprotective-focused studies using herbal medicine in PubMed database and finally 44 papers were included. The type of materials, formation of experiments, type of herbal medicine, their action and mechanisms, and type of cancer were analyzed. Results and conclusion: The number of studies on radioprotective effects of herbal medicine has increased since 2000. The main formation of experiments was clinical study and the portion was 45% and the proportion of prescription research was 51% and the research using herbal product was 25%. Herbs and prescriptions having the effects of tonifying and nourishment were used the most. Most of herbal medicine in this study can enhance immune function, increase anti-oxidant effect, regulate cell cycle and increase sensitivity to radiotherapy. This study will provide useful information on development of herbal medicine having radioprotective effects.

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Components of an anticancer diet, dietary recommendations and the Bill Henderson protocol

Cynthia Mannion (1), Stacey Page (1), Marja Verhoef (1), Laurie Heilman Bell (1)
(1) University of Calgary

Background: The Bill Henderson Protocol (BHP) is an alternative, dietary approach to the self management and treatment of cancer. The primary components are the daily intake of raw fruits and vegetables, and a cottage cheese and flaxseed oil mixture. It recommends restriction of alcohol, meat, gluten and dairy products and advocates supplements such as beta glucan, barley grass, green tea extract, multivitamin and mineral, L-lysine, L-proline and Vitamin C. The following assessment provides the first in depth analysis of the BHP, not before described in the scientific literature.

Objectives: A summary of relevant evidence concerning the anti-cancer fighting properties of individual components is presented. Suggested supplements are examined in relation to the Dietary Reference Intakes (DRI) to see if the amounts suggested fit with evidence based recommendations.

Results: Vitamin A, C, B6, niacin, magnesium and manganese exceed the tolerable upper limit (UL). Vitamin K, B12 thiamin, riboflavin, pantothenic acid, biotin and chromium do not have a UL established, but caution is advised when exceeding recommended daily amounts (RDA). Their BHP recommended intakes exceed the RDA in some cases by 100 times.

Conclusion: Caution must be applied when implementing the BHP for cancer cure or treatment. Consumers require guidance on the ability of this protocol to meet their individual nutritional requirements. Combinations of these nutrients in excess may result in adverse effects. Similar to other therapeutic diets, the BHP presents a regimen attractive to those in need of hope, but is not firmly established as a valid intervention.

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Case-control longitudinal study of decision-making in breast cancer treatment

Emily McKenzie (1), Marja Verhoef (1), Andrea Mulkins (1), Sarah Rose (1), Hal Gunn (2), Chris Bajdik (3), Dean Ruether (4), Jawaid Younus (5)
(1) University of Calgary, (2) University of British Columbia, (3) BC Cancer Agency, (4) Tom Baker Cancer Centre, (5) London Regional Health Sciences Centre

**Background:** Some women decide to decline conventional cancer treatments recommended by their doctors, yet the reasons why have not been well-researched.

**Objectives:** 1. Describe women who receive treatments (CAM and conventional) for breast cancer. 2. To examine within-person changes and between-person differences over 2 years.

**Methods:** Forty women diagnosed with stage 0-III breast cancer within the past first years who declined one or more conventional treatments and use CAM (Cases), are matched to women who accepted all recommended conventional treatments, and may or may not also use CAM (Controls). The groups are matched by disease stage at diagnosis, age and province. Questionnaires assess demographic and psychosocial characteristics, including spirituality, quality of life, self-efficacy, distress, and locus of control.

**Results:** Three-quarters of participants are 40-59 years old. At diagnosis, 19, 15, 6 and 1 women were at Stages I, II, III and 0, respectively. Preliminary results show significant effects for spirituality and distress. For spirituality there was an effect of Group at Baseline (p<0.001) and interaction between Group and Time (p=0.032). Scores decreased in Controls and increased in Cases. There was a decrease in distress between baseline and 6 months (estimate = -1.1, p=0.018) and baseline and 12 months (estimate = -1.3, p=0.006) for Controls, but no evidence of change across time for Cases.

**Conclusion:** The results suggest that the two groups may differ at study outset and over time. Results should be interpreted with caution as data collection is not complete for Controls, and time since diagnosis may impact results.

**Acknowledgements:** Project support received from the Canadian Breast Cancer Research Alliance.
Finding culture in integrative medicine: Ethnographic research into the uses of CAM therapies for “hard-to-diagnose” illnesses

Suzanne Morrissey (1)
(1) McMaster University

Background: This paper presents preliminary results of an ethnographic study of the uses of CAM therapies among patients suffering illnesses with symptoms that are deemed insignificant or unrecordable by biomedical standards and bureaucratic codes, or that are complex and overlapping in ways that defy conventional diagnosis and treatment.

Objectives: Conducted in Ontario, the project aims to contribute to a burgeoning qualitative literature that encourages and informs research literacy around CAM therapies for “medically unexplained” syndromes or emerging illnesses that disproportionately affect women such as chronic fatigue, multiple chemical sensitivity, fibromyalgia, autoimmune disorders, celiac disease, and menopause.

Methods: Using ethnographic methods (in-depth interviews, participant observation, and cognitive mapping) to collect data among providers and clients of CAM at naturopathic clinics and sites of integrative medicine, I examine the experiences of exclusion from conventional medical benefits (social and financial) and inclusion in integrative systems of care.

Results and Conclusion: My goal is to present case study data on CAM and integrative treatment outcomes, and on how the language of suffering is reconceived and rewritten to accommodate emerging uncertain illnesses. In particular, I describe the use of CAM for emerging uncertain illnesses to elucidate who chooses CAM and why, in what combination with allopathic medicine, in what instances and to what ends.

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Flower therapy and the Cartesian method

Tamima Mourad (1)
(1) Escola de Enfermagem-Universidade de São Paulo

Background: Flower Therapy in Brazil is conceived as a type of Alternative and Complementary Therapy. Though it has been thoroughly academically investigated, sieved by scientific scrutiny, it has never been regarded from a Cartesian perspective and parameters. The central issue, which was initially identified in scientific researches, was the constant impasse caused by the direct implementation of empirical exercise in researches; that along with scientific instruments of evaluation imported from other disciplines generated frustrating results. The placebo levelled with the use of flower essences. In such studies, the implemented research instrument was meant to test the active ingredient of the flower essences, which logically, levelled with the placebo—at ground level.

Objectives: To delineate and define the conceptual structure that configures the therapeutic process in Flower Therapy within a Cartesian conceptual framework.

Methods: The Cartesian methodology implemented in this type of research, transfers the researcher’s focus from the flower essence to the therapeutic process, envisaging the process as a whole, instead of isolating one of the constituents of a triangular therapeutic relationship.

Results: The therapeutic cycle was defined as a triangular relationship: patient, therapist and flower essence. Along with the respective definition of roles within the therapeutic relationship, the vocation, intention, profile and space where the relationship had to be defined. As a result, five distinct chronological phases of the therapeutic process were established.

Conclusion: The five distinct successive phases identified are crucial to the evaluation of this therapeutic mode, which must be understood and evaluated as a process instead of having constituents of the therapeutic relationship or phases evaluated in isolation only. This Cartesian exercise has proven to be significant and functional to establish therapeutic guidelines for research, yielding results consistent to what was observed by researchers throughout the study. It also enables a theoretical-methodological framework compatible with the praxis—both necessary to demonstrate results and to establish guidelines for the recognition of this therapeutic mode.

Acknowledgements: No acknowledgements identified.
The I-MED index: Developing and grounding the hypothesis of healing

Andrea Mulkins (1), Marja Verhoef (2)
(1) Tzu Chi Research Group, (2) University of Calgary

Background: The I-MED Index, designed to be a universal instrument assessing five levels of healing (physical, energetic, emotional, subconscious, spiritual), is based on the Hypothesis of Healing (HH). When pretesting the instrument, we discovered that the way participants experience healing in their lives was not as straightforward and simple of a process as the HH suggested. A review of healing theories found limited consistency in the literature, specifically with respect to the ‘dimensions’ of healing. Wording of these dimensions in the literature was also found to be more abstract than how people talk about and experience healing, thus making it difficult to label and operationalize these dimensions.

Objectives: To test and further develop the HH theory by 1. exploring how participants conceptualize healing and 2. identifying what healing domains they feel are most relevant to their experiences.

Methods: In-depth, semi-structured interviews were conducted with 35 individuals with previous healing experiences at two wellness centers in Vancouver BC. Content analysis and thematic coding were utilized to analyze the data.

Conclusion: Themes relating to cause of illness, perception and meaning of the healing experience and hierarchy of healing helped to further develop the HH. Discrepancies between healing theories in the literature and participants ‘healing experiences have been identified such as the inclusion of social healing in the hierarchy and the essential roles that energy, self-esteem and self-acceptance play in the healing process.

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Integrative medicine: Results from a national survey of family doctors’ attitudes and knowledge about complementary medicine

Maria Pirotta (1), Vicki Kotsirilos (2), Jared Brown (3), Tessa Morgan (3), Margaret Williamson (3)
(1) University of Melbourne, (2) General Practitioner, (3) National Prescribing Service

Background: Complementary medicine (CM) use by the public and family doctors/general practitioners (GPs) is widespread in Australia.

Objectives: We aimed to explore differences in attitudes and knowledge about CM between GPs who self report practicing integrative medicine (IM) and those who do not.

Methods: A cross-sectional self-completion survey was mailed to a random national sample of 4,032 Australian GPs. After providing a definition of CM, questions were asked about demographics, CM attitudes, whether doctors considered themselves IM practitioners, and knowledge about certain commonly used CMs’ side-effects and interactions.

Results: 1178 (29.4%) questionnaires were returned. One-third self-identified as practitioners of IM. IM doctors’ attitudes about CM were generally more positive and less sceptical than non-IM. Most respondents were not able to correctly identify common side-effects and potential interactions with glucosamine, black cohosh, Ginkgo biloba. Self-identified IM practitioners, while still doing poorly in this knowledge question, had better knowledge than non-IM doctors. When tested by who had recommended each CM and who had not, there was no statistical difference in knowledge.

Conclusion: This study found that many GPs incorporate aspects of CM into their armamentarium. However, there was little difference in knowledge between GPs who identified as being ‘IM’ practitioners and those who do not. Of concern, most GPs were unaware of the potential interactions and side-effects of three commonly used CM, even those who actively recommended their use to patients. There is an urgent need for GPs to learn more about commonly used CM, including issues about evidence and safety.

Acknowledgements: Project support received from the National Prescribing Service.
Interim analysis of participants in the BC Cancer Agency’s Complementary Medicine Education and Outcomes (CAMEO) Program

Antony Porcino (1), Lynda Balneaves (2), Eric Wong (2), Margurite Wong (2)  
(1) CAMEO Research Program, (2) University of British Columbia, (3) BC Cancer Agency

Background: The Complementary Medicine Education and Outcomes (CAMEO) research program opened at the BC Cancer Agency (BCCA) in April 2008 to address CAM information and decision support needs of BCCA patients and health care providers (HCPs) by providing a variety of information, education and decision-support programs.

Objectives: To understand the type of individuals contacting CAMEO, their information and support needs, and interventions provided.

Methods: All participants contacting the CAMEO program are logged into a database, capturing demographic variables, the contact reason, the CAM information/support requested, and the intervention provided. Descriptive statistics and content analysis were used for the analysis.

Results: Of the 464 participants in the database to date, 60.1% are patients, 20.3% support persons, 17.9% HCPs, and 1.7% CAM practitioners. The reasons for contacting CAMEO include: 1) General and specific questions about CAM therapies; 2) Finding and evaluating CAM information; 3) Working with CAM practitioners; and 4) Requesting other information. The first three categories represented 38.1% of all initial contact. The latter category captured pragmatic reasons for contacting CAMEO, such as registering for research projects and courses.

Conclusion: The CAMEO program is increasingly being contacted for information provision and decision support by a variety of individuals with a range of information needs demonstrating its relevance and viability. Findings from this analysis will inform existing and future CAMEO interventions. Additionally, the findings are important in identifying how interventions should be prioritized and made available as a crucial and much-needed part of standard care within conventional cancer care settings.

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Research on treatment of lung cancer with Chinese medicine based on clinical practice and research

Paymon Sandrolsadot (1), Shadi Sarebanha (1), Chen Xin Yi (1)
(1) Beijing University of Chinese Medicine

Background: For most complementary and alternative medicine interventions, the absence of a high-quality evidence base to define good practice presents a serious problem for clinicians, educators, and researchers. The Delphi process may offer how to establish good practice guidelines.

Objectives: To use a modified Delphi to develop good practice guidelines for a feasibility study exploring the role of Chinese herbal medicine (CHM) in the treatment of lung cancer. To compare the outcomes from Delphi with data derived from a systematic review of the Chinese Language database as well as relevant published books.

Methods: An expert group including seven Professors of Beijing University of Chinese Medicine (BUCM) was convened. They were given a questionnaire containing 50 questions. What they answered was rated on a 1-7 Likert scale. Statements with a median score of 5 and above were regarded as demonstrating consensus. The answers were then contrasted with comparable data from a review of Chinese language reports in the CNKI (1980–2009) which is one of the Chinese scholarly databases through BUCM library website as well as published articles on PubMed database. Also we compared the answers with five published books about lung cancer in Chinese medicine textbooks.

Results: The Delphi guidelines demonstrated a high degree of congruence with the information from the Chinese language databases and also the relevant published books.

Conclusion: In the absence of rigorous evidence, Delphi offers a way to synthesize expert knowledge relating to diagnosis, patient management, and herbal selection in the treatment of lung cancer.

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The development, component parts, and models of care of integrative oncology: A scoping review

Dugald Seely (1), Sarah Young (1), Laura Weeks (2), Isabelle Gaboury (3)

(1) Canadian College of Naturopathic Medicine, (2) Ottawa Hospital Research Institute, (3) University of Calgary

**Background:** There is a growing acceptance of and interest in integrative oncology.

**Objectives:** To better understand facilitators and barriers to integrative oncology through commonalities and differences in the components of care, and dynamics of, care within these clinics.

**Methods:** We conducted a scoping review of eight electronic databases from inception to March 2010 for papers that included data on integrative oncology clinics. For inclusion, papers had to describe: the addition of complementary care to conventional cancer care in the service of cancer patients and survivors. Data comprising 88 separate elements was extracted according to six main concepts including: ‘description of the article’, ‘description of the clinic’, ‘components of care’, ‘clinic organizational structure and behaviour’, ‘patient interactions through the clinic’, and ‘measurable outcomes employed’.

**Results:** A broad screen of 828 records resulted in 34 being included in the scoping review. A total of 18 integrative clinics providing care to cancer patients and survivors were described. Sixty percent of the centres (n=11) seek to conduct research, while the rest did not report on this aspect. Nearly 40% (n=7) provide conventional care on location in addition to complementary medicine whereas four (22%) provide only complementary care and the remaining eight (45%) reported a process to enable collaboration with conventional practitioners. Compensation patterns, funding, organizational structure, patient demographics, practitioner accreditation and training and clinical outcomes were poorly reported.

**Conclusion:** There are several examples of models of integrative oncology care that suggest distinct models operate within the UK and USA. There is a lack of information regarding facilitators and barriers to the development and sustainability of such integrative oncology clinics.

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Effect of music therapy on depression symptoms and cognitive function in non-demented elderly people: A randomized, controlled study

Miaozun Shih (1), Yuan-Han Yang (2)
(1) FGS Compassion Foundation, (2) Kaohsiung Medical University Hospital

Background: Music therapy has been used to stimulate brain functions to modify the cognition, mood, behavior and global function. The therapy has been considered an alternative therapy to those in dementia, such as Alzheimer disease. However, its effect on the normal non-demented elderly population is still unknown.

Objectives: The objective of this study is to investigate the effects of Buddhist Hymns on the cognitive function and depressed mood in the non-demented elderly population.

Methods: This was a longitudinal, single-centre, comparative, randomized controlled study, with blinded assessment of its results. The subjects were followed up at week4 (W4) and week12 (W12). With the group of undergoing music therapy, Buddhist Hymns were played for 30 minutes every day for one month continuously. AD8 is a screening test to detect the early cognitive changes and to exclude the dementia subjects. Psychometrics, Mini-Mental Status Examination (MMSE) and Geriatric Depression scale (GDS) were performed before and after the music therapy at the following 1st and 3rd month visits.

Results: The music group (M, n=30) showed a significant improvement in GDS scale at W4 and W12 (p<0.001). Controlled group (C, n=30), p<0.05 at W4 and the sustained effects were obvious p<0.001 at W12. For the cognitive function, MMSE(M) score improved at W4 without significant changes (p>0.05), but become worse at W12 (p<0.05) and MMSE(C) became worse at both W4 (p>0.01) and W12 (p<0.05).

Conclusion: The results are courageous for further investigation of depressed mood, cognitive and other cerebral function with a larger population size in the future.

Acknowledgements: No acknowledgements identified.
Investigating the feasibility of integrative medicine in a conventional oncology setting: Yoga therapy as a treatment for breast cancer survivors

Suzanne Slocum-Gori (1), Arminee Kazanjian(1), Fuchsia Howard (1), Lynda Balneaves
(1) University of British Columbia

Background: A majority of cancer survivors experience debilitating effect(s) related to their cancer diagnosis and treatments across physical, psychological, social and spiritual domains. These effects are particularly prevalent in breast cancer patients who receive multiple treatments over an extended period of time. Timely and innovative solutions are needed to address the adverse treatment-related effects and often disjointed services that breast cancer patients face. Recent studies suggest that the majority of breast cancer survivors are utilizing complementary and alternative medicine at some point along their cancer trajectory. In recent years, scientists and clinicians have examined the effects of yoga therapy among cancer patients and survivors.

Objectives: The current study examined the feasibility of implementing yoga therapy as a treatment service for breast cancer patients within a large urban cancer center in Canada.

Methods: A mixed-methods approach that included focus groups and self-reported surveys with health care providers (HCPs) and breast cancer patients was utilized in this research.

Results: Overall, results indicated that breast cancer patients and HCPs were supportive and eager for the implementation of a yoga therapy program. Furthermore, the results identified the a) benefits of integrating a yoga therapy program, b) factors that impact acceptance levels and c) essential intervention components.

Conclusion: The findings of this study are currently being utilized to inform 1) a pilot study of a yoga therapy intervention, and 2) the development of integrative treatment services for breast cancer patients.

Acknowledgements: Project support received from CIHR and MSFHR.
Choosing natural health products for osteoarthritis: Where's the evidence?

Lauren Sule (1), Teresa Tsui (1), Heather Boon (1)
(1) University of Toronto

Background: People with osteoarthritis (OA) self-medicate with natural health products (NHPs), which have varying amounts of scientific evidence supporting their efficacy.

Objectives: The objective of this project was to conduct a qualitative content analysis of transcripts of interviews designed to explore consumers’ perceptions of scientific evidence and other information sources in their decision to use NHPs in the management of their OA symptoms.

Methods: Twenty-five individuals with OA who reported using at least one NHP were previously recruited and completed in-depth semi-structured interviews. Interview transcripts were independently coded using constant comparative content analysis by two or three investigators who met regularly to ensure consensus on coding decisions. NVivo software was used for data management.

Results: Participants relied upon recommendations from friends and family, healthcare providers, and health food store employees, along with information from websites, newspapers and magazine articles in their decisions about NHPs for OA. The primary and most trusted information sources were friends/family and healthcare professionals—mainly doctors, pharmacists and CAM providers. Anecdotes about NHP benefits were considered "better" sources of evidence than scientific research. The majority of participants did not use scientific evidence, and it played only a small role in the decision-making process. No differences were observed between participants who selected NHPs having a high level of scientific evidence support, and those with a low level of support.

Conclusion: The most important information sources were friends, family and healthcare providers. Scientific evidence is not an important factor in the consumer decision-making process.

Acknowledgements: Project support received from the Advanced Foods and Materials Network.
**Ginkgo biloba for the treatment of vitiligo vulgaris: An open label pilot clinical trial**

Orest Szczurcko (1), Heather Boon (1)
(1) University of Toronto

**Background:** Vitiligo is a hypopigmentation disorder with significant psychological impact.

**Objectives:** To assess the feasibility of conducting a randomized controlled trial of ginkgo for the management of vitilago. Methods: Twelve participants 12 to 35 years old were recruited to a prospective open-label pilot trial and treated with 60 mg of standardized G. biloba twice daily for 12 weeks. The criteria for feasibility included successful recruitment, 75% or greater retention, effectiveness and lack of serious adverse reactions.

**Results:** Eleven participants completed the trial with 85% or greater adherence to protocol. The total VASI score improved from 5.0 to 4.5 (P = 0.021). VETF total vitiligo lesion size decreased from 5.9% to 5.6% (P= 0.102) from baseline to week 12. VETF staging score improved from 6.6 to 5.8 (P=0.101), and the VETF progression score improved from 2.7 to -1.2 (P=0.00036). Progression of vitiligo stopped in all participants; total VASI indicated an average repigmentation of vitiligo lesions of 15%. The platelet count was on average 262 at baseline and increased to 284 at week 12 (range 145-400), PTT decreased from an average of 36.5 to 34.6 (range 26-37 seconds), and the INR remained stable at an average of 1.15 (range 0.9-1.3).

**Conclusion:** Ingestion of 60 mg of Ginkgo biloba twice daily was associated with significantly improved total VASI scores and a trend towards improvement on VETF lesion area and staging. A RCT is recommended since the feasibility criteria were met after expanding the age limit.

**Acknowledgements:** Project support received from IN-CAM.
The application of dynamic systems theory to traditional Chinese medicine

Lisa Taylor-Swanson (1)
(1) Abundant Health, PLLC

**Background:** Traditional Chinese Medicine (TCM) has recently been conceptualized as a whole system of medicine. This viewpoint requires that TCM theory and applicable modalities (e.g., acupuncture, Chinese herbal medicine, moxibustion, etc.) are incorporated in research design. It is difficult to translate TCM system ideas into a western scientific perspective. Accordingly, this paper proposes using a western systems approach, dynamic systems theory, as bridge between east and west.

**Objectives:** To demonstrate parallels in TCM and dynamic systems theories.

**Results:** Systems and TCM theories are contextual. Both examine relationships between system components within the context of the larger whole. In TCM, eight principle theory is used to determine patterns of disharmony in a patient. When a patient receives TCM, a perturbation has been introduced into his/her system, and not necessarily in response to specific symptoms, but rather to the pattern of disharmony. This perturbation will affect a phase shift to a new dynamic configuration that may include a remediation of the symptoms along with other salutary changes. Change occurs at the system level rather than the symptom level. In systems science, epistemology (knowledge generation) is relational, from the perspective of the observer who is part of the system. In TCM clinics, epistemology is rooted in patient-practitioner relationships.

**Conclusion:** TCM and dynamic systems theories share concepts of interrelated non-hierarchical system components which are best understood by examining relationships between those components. Dynamic systems theory may serve as a way to translate TCM terminology and theory to biomedical scientists.

**Acknowledgements:** No acknowledgements identified.
Case study of adolescent primary dysmenorrhea treated with TCM

Lisa Taylor-Swanson (1)
(1) Abundant Health, PLLC

**Background:** Adolescent primary dysmenorrhea (PD) is typically treated with ibuprofen or oral contraceptives. Several studies have been conducted on acupuncture or Chinese herbal medicine to treat PD. No study to date has explored adolescent PD using a whole systems perspective. This case study documents one adolescent’s experience receiving Traditional Chinese Medicine (TCM) for PD.

**Objectives:** To report one outcome and apply dynamic and whole systems theories to the study of adolescent PD.

**Methods:** One patient and her parent consented to treatment and participation in the study. The patient was seen bi-weekly for five months and given acupuncture, Chinese herbal medicine, diet therapy and acupressure advice according to TCM differential diagnosis. Pain ratings, changes in TCM diagnosis and all clinical symptoms were recorded in her chart. The chart and a 6-month follow-up interview were analyzed with content analysis.

**Results:** This patient experienced two cycles with decreased dysmenorrhea followed by a complete cessation of PD which was lasting six months after cessation of treatment. The TCM diagnosis changed from Liver overacting on Spleen with concurrent moderate blood stagnation to one of mild blood stagnation and mild Spleen Qi deficiency. The patient reported an increase in self-confidence due to increased sense of well-being. Her mother reported a significant change in her daughter’s ability to interact socially and the absence of PD, headaches and digestive problems. **Conclusions:** This case demonstrated systemic changes as well as cessation of PD and other symptoms. A study using whole and dynamic systems theories with larger samples is needed. **Acknowledgements:** No acknowledgements identified.
Using the means-end chain approach to understand the role of "scientific" evidence in natural health product consumer decision making

Teresa Tsui (1), Heather Boon (1), Murray Krahn (1), Andreas Boecker (2), Natasha Kachan (1)
(1) University of Toronto, (2) University of Guelph

Background: Natural health products (NHPs) are commonly self-medicated for osteoarthritis-related pain. Objectives: To compare participants using products with scientific evidence support and those using products lacking scientific evidence support using the means-end chain (MEC) decision-making approach.

Methods: A convenience sample of 25 participants with self-reported osteoarthritis (OA) was identified. Thirteen had consumed NHPs with scientific evidence of efficacy for OA (glucosamine or chondroitin) only, while 12 had consumed NHPs lacking scientific evidence. Using the laddering interview technique linked with the MEC approach, salient product attributes (e.g., natural source) were elicited; these were linked with associated consequences (e.g., reduction in pain) and underlying values (e.g., quality of life). Hierarchical value maps were generated to depict the decision-making processes. Additional qualitative questions probed the role of scientific evidence in the decision-making process and content analysis was performed to identify thematic similarities and differences between participants in the two evidence categories.

Results: The dominant decision-making chain between participants in the two evidence categories was similar. Scientific evidence was an NHP product attribute mentioned by about half of our participants while almost all participants initially learned about NHPs from a trusted individual such as a friend. Very few participants in either evidence category consulted evidence-based sources. More participants using products with scientific evidence consulted with a CAM practitioner than those using products with low levels of scientific evidence.

Conclusion: There were essentially no differences in how consumers in our two evidence categories incorporated scientific evidence into their choice of NHPs for OA.

Acknowledgements: Project support was received from the Advanced Foods and Materials Network.
Measurement of Jing Well acupuncture points in chronic pain states compared to a pain free group

Linda Turner (1,2)  
(1) Langara College, (2) University of British Columbia

Background: Research in the area of energy based healing as a treatment for pain can only be furthered by the use of laboratory models which allow for more rigorous and controlled studies. Jonas and Crawford (2003) recommend a biological model for exploring technologies to measure low-level energy emission from living things.

Objectives: The purpose of this project was to compare meridian measurements in a control group with a pain level of 0 and an experimental group with a pain level of 0.

Methods: Thirty-two subjects with rheumatoid arthritis and a pain level of at least 4 (0-10 scale) were compared to twenty-eight subjects who were pain free. The measurements from the Prognos ohmmeter, a device to measure skin resistance at Jing Well points, were compared to heart rate, heart rate variability, blood pressure, Pain Catastrophization Scale, McGill Melzack Pain Scale and the Profile of Mood States.

Results: There were significant differences between the experimental group and the control group related to all traditional measures except heart rate variability. There was a significant difference between Jing Well measurements in the Bladder, Gall Bladder and Small Intestine Meridians with a multivariate F for groups of (F = 2.217, DF = 6) = .05 between the pain level of 4 and the pain free group.

Conclusion: Prognos measurements were significantly correlated with total pain and some dimensions of the Profile of Mood States. It was concluded that the Prognos Ohmmeter detects skin resistance differences between a pain level of 4 and 0 and may be useful in detecting the results of acupuncture or energy based healing.

Acknowledgements: Project report received from the Lotte & John Hecht Memorial Foundation.
The effect of Reiki on pain in women after elective caesarean section: A double blinded randomized controlled trial

Sondra vanderVaart (1), Dr. Howard Berger, (2) Carolyn Tam, (3) Y. Ingrid Goh, (3) Violette Gijsen, (3) Dr. Saskia de Wildt (3) Dr. Anna Taddio, (1) Dr. Gideon Koren (3)
(1) University of Toronto, (2) St. Michael’s Hospital, (3) The Hospital for Sick Children

Background: Reiki is an ancient Japanese form of healing where the practitioners transfer healing energy through light touch and positive healing intention. Although an estimated 1.2 million Americans use Reiki to reduce pain or depression, there is a lack of strong evidence supporting its effectiveness. Moreover, a recent systematic review showed existing studies to be of poor methodological quality. A common limitation of these studies is the lack of blinding. To overcome this issue, we used remote Reiki, a technique where advanced Reiki practitioners can transfer healing energy through intention alone.

Objectives: To assess the effectiveness of Reiki in reducing pain following an elective Caesarean section.

Methods: In this randomized, double blinded study, women who underwent an elective C-section were allocated to receive either usual care (control, n=40) or three sessions of remote Reiki in addition to usual care (n=40). Pain was assessed using a visual analogue scale (VAS). The primary endpoint was the Area Under the VAS-time Curve (AUC) for days 1 to 3. Secondary measures of pain included: proportion of women who required opioid medications, dose of opioid medication consumed, rate of healing and vital signs (heart rate, respiration rate and blood pressure).

Results: AUC for pain was not significantly different for the Reiki group compared to the control group (mean ± SD; 212.1 ± 104.7 vs. 223.1 ± 117.8; p=0.96). There were no significant differences in opioid consumption or rate of healing. Compared to the control group, the Reiki group had a small but significantly lower heart rate 4 hours post surgery (74.3 ± 8.1 bpm vs. 79.8 ±7.9 bpm, p=0.003) and systolic blood pressure on day 3 (106.4 ± 9.7 mmHg vs. 111.9 ± 11.0 mmHg, p=0.02).

Conclusion: Remote Reiki had no significant effect on pain following an elective C-section.

Acknowledgements: No acknowledgements identified.
Describing and understanding cancer patients’ pathways of treatment and care

Marja Verhoef (1), Mary Koithan (2), Andrea Mulkins (1), Lynda Balneaves (3), Emily McKenzie (1), Angela Davidson (2), Sara Warber (4)
(1) University of Calgary, (2) University of Arizona, (3) University of British Columbia, (4) University of Michigan

Background: Cancer treatment decision-making is a complex process that takes place over time, is impacted by a range of variables, and consists of a variety of treatments.

Objectives: To describe patients’ pathways of treatment and care.

Methods: Patient characteristics, treatment decisions (conventional, complementary/alternative and self-care) and salient life events are followed over time using qualitative and quantitative methods.

Results: So far, thirty-three participants aged 18-75 with a first-time diagnosis of stage I-III breast or prostate cancer have been recruited in Canada and the US. Pathways develop at an early stage in the cancer care trajectory and are often enduring. Emerging pathways include: 1. Aggressive Conservative Path: choosing an aggressive conventional treatment plan. After treatment completion individuals may use CAM to regain strength and wellness. 2. Reasoned Conventional Path: having little interest in CAM, individuals thoroughly assessing conventional treatments presented by physicians. 3. Reasoned Integrative Path: believing in the benefits of both conventional and CAM treatment and focusing on curing as well as healing. 4. Reasoned Alternative Path: making major life changes after diagnosis and preferring natural therapies. Factors influencing pathways include: motivation for treatment, treatment cost, pre-diagnosis life or family events, philosophy of healing, nature of relationship with healthcare providers, satisfaction with cancer treatment, and beliefs.

Conclusion: Literature about treatment decisions and care pathways focuses on the choices collected from medical records rather than as explained within the context of individuals’ lives. Our data suggest that decision paths are complex and influenced by a host of variables previously unexplored.

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Natural health product regulations: Industry and government lessons learned

Rishma Walji (1), Ivy Bourgeault (2), Robin Marles (3)
(1) McMaster University, (2) University of Ottawa, (3) Health Canada

Background: The NHP regulations attempt to address broad safety and quality concerns by placing legal requirements on the NHP industry that are similar to those currently in place for other regulated health products. The NHP industry is unique because their products were already available over-the-counter when the regulations were instituted.

Objectives: The aim of the research was to enhance understanding of the role of natural health product (NHP) manufacturers and regulators in NHP safety monitoring and licensing during a time of regulatory change.

Methods: This project involved first a documentary review and policy analysis of current literature, legal documentation and policies of manufacturer responsibilities for NHPs compared to conventional drugs in Canada as well as a comparison to international NHP regulations. Second, key informant interviews were conducted with representatives from various manufacturing corporations and regulatory departments in Health Canada. These interviews were transcribed and analyzed using content analysis to identify dominant themes.

Results: The research outlines key lessons learned from governmental experience with respect to the process of implementing the regulations. It also highlights important challenges and obstacles from manufacturer perspectives associated with compliance to the regulations. Issues such as license application processing procedures, deadlines, exemptions, definitions, and enforcement were significant concerns that needed to be addressed during the regulatory transition.

Conclusion: There have been several challenges with implementing and enforcing the NHP regulations. This work has important implications in understanding industry compliance and regulatory practice, especially in context with on-going difficulties in safety monitoring and quality control.

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Prospective meta-analysis in CAM research

Dawn Walker (1)
(1) University of Nottingham

**Background:** Results from systematic reviews (SRs) are regarded as the ‘gold standard’ of evidence by healthcare policy-makers. SRs are thorough literature searches which incorporate methods, e.g. inclusion criteria, to prevent bias. A benefit of SRs is that data from different trials reported in the included papers, if using a common measure of effect size, can be amalgamated using meta-analysis (MA). The results from the MA are more powerful estimates of the true effect size than those derived from a single trial due to the MA being based on different trials, crossing geographical boundaries, populations, trial conduct, etc. As MAs pool data it also results in a larger overall sample size as it includes the populations from all of the included trials, therefore reaches higher statistical power to detect an effect. Although this type of analysis lends itself to CAM research, as many trials reported are small scale, often MA cannot be conducted on the data obtained from included papers as studies are often heterogeneous. A way this can be overcome in research is by collaborating using a Prospective Meta-Analysis (PMA) design.

**Objectives:** To introduce a new method for developing a data base of empirical evidence and to encourage discussion and collaboration to take this idea forward.

**Methods:** In PMA, trials are identified, evaluated, and determined prior to publication to establish eligibility for the post-trial MA. This relies on the formation of collaborative groups who will liaise on research protocols during the duration of the research, thus allowing pre-standardization of information required for the post-hoc MA.

**Results:** This presentation will help conference attendees to bear this methodology in mind when thinking about a new piece of CAM research. It is also hoped that PMA collaborations will be organized during the conference.

**Conclusion:** PMA is a way of building the CAM evidence base, in the absence of being able to conduct large, full-scale trials.

**Acknowledgements:** No acknowledgements identified.
Current status and prospects of traditional medical market in Korea

Jonghyang Yoo (1), Eunsu Jang (1), Siwoo Lee (1), Jongyeol Kim (1)
(1) Korea Institution of Oriental Medicine

Background: Korea has a long history of traditional medicine, so it has a strong position in research and development of traditional medical market compared to other countries. Study on the status of traditional medical services in the marketplace is essential to predict the future of traditional medicine.

Objectives: This research aims to know the current status and prospect of traditional medical market to provide sources in setting a development strategy and making a policy on the traditional medicine in Korea.

Methods: This research categorized 11,611 clinics registered in telephone directory as of 2008 by region and some clinics were extracted with simple random method. The inquiry was made with questionnaires and analyzed on the base of frequency.

Results: 1. The number of the employee in a clinic were slightly decreased from 2.9 in 2005 and 2006 to 2.8 in 2007. That of the patients also showed a downward tendency from 11,811 in 2005 through 11,716 in 2006 to 11,344 in 2007; 2. Approximately 92% of the responses made a negative diagnosis on the traditional medical market and 21% of responses indicated the overall economic recession as a primary reason in their opinions; and 3. About 29% of responses presented the extension of medical insurance on traditional medicine as a prior policy.

Conclusion: Based on the survey, the prospect of traditional medical market is positive, but the effort of the people in traditional medical system and the systematic support from government are required to activate the stagnated traditional medical market.

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PedCAM

Safety and efficacy of a compound natural health product in children with ADHD: A feasibility pilot

Kieran Cooley (1), Umesh Jain (2), Dugald Seely (1), Anna Tadio (3), Sunita Vohra (4), Heather Boon (3)
(1) Canadian College of Naturopathic Medicine, (2) Center for Addiction and Mental Health, (3) University of Toronto, (4) University of Alberta

Background: There is inconclusive evidence suggesting nutritional supplementation can benefit children with attention deficit hyperactivity disorder (ADHD); however, whether this benefit will be clinically significant is unknown.

Objective: To investigate the feasibility of conducting a clinical trial designed to investigate the efficacy of a compound nutritional product to decrease the severity of clinical symptoms experienced by children with ADHD, possibly by correcting relative nutrient deficiencies.

Methods: A 10 week, open-label, pilot study investigating a chewable product containing weight based doses of zinc citrate (15-35mg/d), magnesium dilactate (150-350 mg/d), pyridoxine hydrochloride (30-70mg/d) and ascorbic acid (150-250 mg/d) taken twice daily with meals was conducted. Parents' responses to the Connors 3, and SNAP-IV questionnaires, as well as participants' serum zinc, and red blood cell magnesium levels (RBC Mg) were collected at baseline and 10 weeks. Feasibility was assessed based on recruitment, retention, data quality, effectiveness trends and safety parameters.

Results: 90 inquiries resulted in screening of 40 children, 26 enrolled and 21 completing the study. Medication compliance was >80%. Mean improvements on Connors 3 (-28.9%), and SNAP-IV total (-26.4%) were clinically meaningful (p<0.001); but did not correlate strongly with changes in serum zinc and RBC Mg. One resolving skin rash and 5 emotionally challenging events related to the blood draw occurred.

Conclusion: Design and conduct of a future RCT is feasible and warranted.

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Feasibility and acceptability of parent-delivered massage RCT in pediatric oncology

Trish Dryden (1), Andrea Laizner (2), Dawn Davies (3), Sunita Vohra (4), Stacey Shipwright (1), Ronda Blasco (4), Cheryl Locicero (3), Elizabeth Barberree (5), Linda Churcher (3), Janet Kahn (6), Lyse Lussier (7)
(1) Centennial College, (2) McGill University, (3) Stollery Children’s Hospital, (4) University of Alberta, (5) Massage Therapist Association of Alberta, (6) University of Vermont, (7) Enfants et Familles

**Background:** Having a child diagnosed with cancer is devastating for families and often parents wonder what they can do to support their ill child. Parent-delivered massage is an option for parents.

**Objectives:** A pilot study sought to test the feasibility and acceptability of a parent-delivered massage program in a randomized-clinical trial for children (6 to 18 yrs old) diagnosed with cancer.

**Methods:** 24 families were to be recruited into intervention or wait-list control groups. After baseline measures were collected, the intervention began including in-person training by a massage therapist (MT) and training materials including an instructional DVD. Massage was to be delivered at convenient times for parent and child over a 12-week period with telephone support from the MT. Parents and children were to complete study questionnaires and a parent debriefing interview was held at the end of 6 and 12-weeks. Wait-list controls were provided intervention 6-weeks after randomization.

**Results:** 19 parent-child pairs were recruited (8 intervention, 11 control); however, 9 families withdrew (3 from intervention and 6 from control). Debriefing interviews were easier to arrange than obtaining self-report questionnaires/logs. Parents reported feeling better about what they could do to provide comfort to their child, and also reported that massaging their child helped improve their child's sleep, reduce pain and procedural anxiety, and increase parent-child bonding.

**Conclusion:** Parents felt that they had greater control over their child’s illness and felt as though they were part of their child’s health care team. Challenges included parents wanting intervention but not wait-list randomization.

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Investigating the use of CAM among children with Inflammatory Bowel Disease

Maria Gordon (1)
(1) University of Ottawa

**Background:** Canada has the highest rate of inflammatory bowel disease (IBD) in the world (Bernstein et al., 2006). Lindberg and colleagues (2000), estimate 9 of every 100,000 children have IBD. The disease can strike at any time, any age and there is still no cure. To date, there has been very little research concerning chronically ill children's coping styles (Jones, 2006) and the uses of Complementary Alternative Medicines (CAM) and CAM health services by families with a child with IBD.

**Objective:** Families are seeking alternatives to the debilitating side-effects of the prescribed steroidal medications and are experimenting with a variety of CAM. This study aimed to explore their use of CAM and CAM health services and the reasons for their choices.

**Methods:** A qualitative study using one-on-one interviews with families with a child with IBD (aged 7-15 years) was conducted. Families were recruited using a variety of methods including on-line websites and newsletters. The small convenience sample yielded participant families that had children with IBD in various stages of the disease.

**Results:** Interviews revealed insights into the resourceful coping strategies the children and their families created to enable them to cope with the daily demands of the chronic symptoms.

**Conclusion:** Preliminary findings demonstrate that families seek the services of more than two CAM professionals and try at least two different types of CAM. CAM use was often unsuccessfully and parents reverted to using steroidal medications. Few families relied solely on CAM and CAM health services to assist their child with IBD.

**Acknowledgements:** No acknowledgements identified.
The application of acupuncture and Unani herbal medicine in the cases of autistic spectrum disorder

Shariq Khan (1), Md. Alamgir Hossain (2)  
(1) Ayurvedic Medical Degree College and Hospital, (2) Directorate General of Health Services, Gov’t. of Bangladesh

**Background:** ASD (Autistic Spectrum Disorder) is becoming a serious pediatric problem in the present days. There is no concrete / real medical treatment still yet discovered which may recover this disorder. Research works are going on to find out its remedy. Autism is a severe neurodevelopmental disorder that begins at birth or within the first two-and-a-half years of life. It is a spectrum disorder, meaning that it affects people differently. Some children may have speech, whereas others may have little or no speech. Its cause is still a mystery, neurological studies seem to indicate a brain dysfunction. ASD is characterized by deficits in language, social communication, symbolic or imaginative play, cognition and less or no eye contact. Children with autism / ASD usually have secondary problems in behaviour including aggression, irritability, stereotypes, hyperactivity, negativism, volatile emotions, temper tantrums, short attention span and obsessive-compulsive behaviour. There are several research papers, articles etc. that has been published all over the world about the efficacy of Acupuncture and Herbal Medicines.

**Objectives:** Here the objective is to share the experience of applying these methods of therapy on the patients of ASD.

**Methods:** Acupuncture therapy and Unani herbal drugs has been applied to treat the ASD patients.

**Results and Conclusion:** The result of application of Acupuncture and Herbal therapy is variable. In some of cases it gives tremendous improvement within short time but in some cases much time takes to get result.

**Acknowledgements:** No acknowledgements identified.
Development of the LEAP project: An online spirituality-based intervention for adolescent depression

Sabine Moritz (1), Badri Rickhi (1), Patti Paccagnan (1), Mary Kelly (1), John Griffith (2)
(1) CINIM, (2) Spiritual Directions

Background: Given the growing prevalence of adolescent depression, uncertainties regarding efficacy and safety of conventional treatments and the mounting evidence for a role of spirituality in depression recovery, we set out to develop an online spirituality based intervention for clinically depressed adolescents.

Methods: A) Needs Assessment: This included: 1. a literature review, 2. consultations with experts on spirituality and teen mental health and 3. focus groups with youth on media preferences and views on spirituality. B) Framework and Content Development: We compiled an exhaustive collection of spiritual principles from the major traditions of the world, as well as secular organizations, and sorted and categorized these principles until a path of spiritual growth emerged that became the program foundation. Based on the literature review, six key symptoms of teen depression were identified and hypotheses were formulated on how spiritual growth could alleviate these. While the spiritual content development was based on traditional spiritual teachings, materials to bring these teachings to live were largely teen generated. In addition, we included guided imagery and simple meditations tailored towards the program content. C) Website Development: A media company was engaged for the production of the online program. D) Youth Focus Groups: Program content and presentation were focus group tested with youth volunteers.


Conclusion: We produced a youth relevant program to nurture spiritual growth. A pilot study is now underway to evaluate the LEAP program in a depressed teen population.

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Adverse events of medicinal herbs in children and adolescents: A systematic review

Sunita Vohra (1), Denise Adams (1), Hafsa Nasser (1), Paula Gardiner (3)
(1) University of Alberta, (2) University Medical Center

Background: Pediatric herbal use is increasingly common and case reports of adverse events (AEs) are often used to guide practice despite concerns about quality of reporting.

Objectives: i) To systematically review published case reports of pediatric medicinal herb AEs and ii) to assess reporting quality.

Methods: Searches of 7 databases were conducted from inception to June 2009. Full text of potentially included studies were assessed for inclusion using predetermined criteria.

Results: Searches identified 12084 references, of which 107 publications (127 cases), were included. Most (72%) reports were for children under 5 years and most exposure occurred after birth (81%) and through oral ingestion (71%). 99 reports were for single herb products, including Camphor (10), Eucalyptus (8), Lavender and Jin Bu Huan (5 each), Blue Cohosh, Cloves, Fennel, Garlic, Podophyllin, and Tea Tree (3 each), Belladonna, Foxglove, Ginkgo, Kava, and Rue (2 each). Missing information included: identification of herb (9%), concurrent use of other products (74%), medical history (7%), duration of use of product (37%), list of all product ingredients (38%), part of plant used (47%), type of preparation (31%), lab testing of product (61%), and presence of heavy metal in patient blood (91%).

Conclusion: This systematic review assesses the safety of medicinal herbs in children, which is important to practitioners and patients/families in guiding safe use. Assessment of reporting practices may be useful in developing reporting guidelines for herb-related AE.

Acknowledgements: Project support received from the Canadian Patient Safety Institute.
Building a database of pediatric outcomes for CAM researchers

Sunita Vohra (1), Denise Adams (1), Leka Sivakumar (1), Hafsa Nasser, Soleil Surette (1), Lisa Hartling (1)
(1) University of Alberta

Background: High rates of use of complementary and alternative medicine (CAM) in children have prompted increased research, which in turn relies on appropriate outcome measurement tools.

Objectives: i) To develop an inventory of valid and reliable pediatric outcome measurement tools and ii) to identify gaps in outcomes reporting in publications of pediatric randomized controlled trials (RCTs).

Methods: The top 6 general medicine journals and top 4 pediatric journals were searched for pediatric RCTs published since 2000. Two independent reviewers conducted screening and data extraction.

Results: Searches identified 2229 unique references. Screening of 2.5% of references determined that the vast majority (96.5%) would be included, thus full text for all references was obtained. Inclusion screening and data extraction will occur simultaneously and are currently underway. Variables to be extracted for the first objective include: journal type (general versus pediatric), population age, sample size, condition of interest, intervention, control, and primary outcome. Variables to be extracted for the second objective include all outcome measurement tools such as surveys and questionnaires, as well as information on psychometric testing. Results will be presented in November.

Conclusion: This project will serve to populate a database of pediatric outcome measurement tools and will identify gaps in outcomes reporting in pediatric trials published in top journals over the past 10 years, leading to recommendations for improvements in reporting standards.

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An international consensus-based process to develop a pediatric CAM research agenda

Sunita Vohra (1), Denise Adams (1), Shay Pintov (2), Arine Vlieger (3), Kathi Kemper (4)
(1) University of Alberta, (2) College of Management Academic Studies, Rishon Lezion, (3) St. Antonius Hospital, (4) Wake Forest University

Background: Pediatric CAM is a huge field with many unanswered research questions. Identification of priorities would help researchers, funders, and decision-makers.

Objectives: To develop and refine a pediatric CAM research agenda.

Methods: A modified Delphi process to identify important knowledge gaps in pediatric CAM and to develop consensus around research priorities through an iterative process. Four phases were planned: Phase I: email survey to CAM community; Phase II: email survey to published pediatric CAM researchers; Phase III: in-person meeting; Phase IV: email survey to CAM community.

Results: Phase I: 143 participants in eleven countries, of which 58% were practitioners (conventional or CAM), responded to the survey. Phase II: 19/71 (27%) participants, from seven countries, responded. Of these, ten were researchers, six were conventional health care providers, and three were conventional and CAM health care providers. Phase III: Eight participants attended this meeting, and identified the following priority areas: i) safety of CAM therapies; ii) conditions for which conventional medicine lacks effective therapies or they are unsafe or costly, and/or when CAM use is highly prevalent among pediatric patients; iii) promising therapies for these conditions; and iv) identification/development of appropriate outcome measures. Phase IV is underway.

Conclusion: It is hoped that this international consensus-based research agenda will serve as a guide to pediatric CAM researchers, decision-makers and funders to enhance the productivity and meaningfulness of pediatric CAM research internationally.

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The safety of pediatric acupuncture: A systematic review

Sunita Vohra (1), Denise Adams (1), Florence Cheng (1), Hsing Jou (1), Steven Aung (1)
(1) University of Alberta

Background: Despite widespread use, safety of pediatric acupuncture has yet to be described by systematic review (SR).

Objectives: To identify adverse events (AEs) associated with pediatric needle acupuncture.

Methods: 18 databases were searched up to June 2007, irrespective of language. Inclusion criteria were: i) original, peer-reviewed patient data, ii) children from 0-17 years, inclusive iii) involved needle acupuncture, and iv) reported an AE. Full articles of potentially relevant references were retrieved and assessed by two independent reviewers. Safety data were extracted from all included studies.

Results: Searches identified 7262 potentially relevant articles. Of these, 209 were retrieved and assessed for inclusion. Fourteen studies were included and searches of reference lists identified five additional studies for a total of 19. A total of 140 AEs were identified, 133 mild and seven serious. One serious AE was unlikely to be related to acupuncture, leaving six possibly or probably related, including one case each of cardiac rupture, pneumothorax, nerve injury, and three infections. The mild AEs included pain, bruising, bleeding, and worsening of symptoms. Based on the available data we calculated mild AE incidence per patient of 16.3/100 for the RCTs and 6.3/100 for the cohort studies, with a combined incidence of 7.8/100, and corresponding values per treatment of 1.6/100, 0.6/100, and 0.8/100, respectively. This search is currently being updated; new results will be presented in November.

Conclusion: Most pediatric acupuncture-associated AE were mild in severity. These results support adult studies that have determined that acupuncture is safe when performed by appropriately trained practitioners.

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Can n-of-1 be used to evaluate classical homeopathic treatments? An evaluation of the peer reviewed literature

David Brulé (1)
(1) Riverdale Homeopathic Clinic

Background: Research in the field of classical (individualized) homeopathic medicine presents a variety of trial methodology issues. Classical homeopathic approaches involve the individualization of treatment based on the individual patient’s symptom picture. N-of-1 trial methodology is scientifically rigorous and studies treatment of an individual participant. In theory, n-of-1 trials are well suited to studying individualized homeopathic treatment. However, due to the clinically unpredictable carry-over effects of classical homeopathic treatment, n-of-1 trials are often not suitable.

Objectives: To evaluate the peer-reviewed literature for n-of-1 trials whose design may be applicable to classical homeopathic techniques.

Methods: PubMed and Google Scholar were searched using the keywords homeopathy, n-of-1 trials, CAM, and Complementary and Alternative Medicine.

Results: 141 papers were identified, with 13 papers related to CAM, and 1 related to homeopathy. One clinical situation was singled out for further analysis: identically repeated rounds of a therapy (example: chemotherapy treatment).

Conclusion: The clinical situation of repeated rounds of a therapy, such as repeated rounds of chemotherapy treatment, seem to avoid the methodological pitfall of the potential carry-over effects of classical homeopathic treatment interfering with the rigour of the n-of-1 trial design. Subsequent rounds of a therapy may act as a wash-out of the previous round’s treatment thus mitigating carry-over effects. A trial protocol should be developed to assess feasibility of the application of the n-of-1 methodology to the classical homeopathic treatment of side effects of repeated rounds of a therapy such as chemotherapy.

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A randomized placebo-controlled trial of the efficacy of homeopathy as adjuvant in the treatment of pulmonary tuberculosis

Neha Sharma (1), Sadhana Sharma (1), RG Sharma (1)
(1) NMP Medical Research Institute

**Background:** Tuberculosis is a global emergency where long duration of treatment has emerged as a major obstacle in the control of tuberculosis. There is a need for development of new drugs and or shortened therapy.

**Objectives:** The present study was carried out to explore whether any benefit could be achieved by the addition homeopathy to the conventional anti-tubercular chemotherapy.

**Methods:** In a randomized double-blind placebo controlled study, new cases with smear-positive TB (n = 120) were given homeopathy or placebo for 16 weeks in addition to conventional chemotherapy. Patients were followed for 6 months after completing treatment regimen of conventional treatment. Primary outcomes were faster sputum conversion at 8 weeks. Secondary outcomes were weight gain, clinical symptoms, and change in haematological assessment (Erythrocytic sedimentation rate and hemoglobin) after week 8 and week 24. Patients were followed to observe any relapse after 6 months of treatment.

**Results:** The patients treated with homeopathy as an adjuvant therapy along with anti-tuberculosis drugs had a faster clearance of tubercle bacilli from the sputum as compared to the placebo group (P < 0.001), until the eighth week of treatment all patients converted to AFB negative. In placebo group 18.3% remained positive and continued first stage of treatment for next 4 weeks. Compared with the placebo group, the homeopathy group showed significant improvement, defined as increased weight gain and faster reduction of symptoms, such as cough. Change in ESR was significantly higher in the homeopathy (P = 0.0001 and P = 0.0001 for group and time effects) as was the increase in Hemoglobin (P = 0.0001 and P = 0.001 for group and time effects). At follow up, there was no relapse in homeopathy group; where as 11.67% of placebo group had relapsed converted in sputum positive.

**Conclusion:** These findings provide preliminary evidence that homeopathy may be a promising adjunctive therapy for patients with tuberculosis. Faster conversion of sputum should prevent the development of resistant mutants.

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