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Integrating CAM Research and Practice: A
Focus on Outcome Measures - Abstracts from
the 3rd Annual IN-CAM Symposium
November 4th & 5th, 2006, Calgary, Canada

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Abstract

The following are abstracts of oral and poster presentations given at the third annual IN-CAM Research Symposium: “Integrating CAM Research and Practice: A Focus on Outcome Measures” that was held on November 4th & 5th, 2005 at the University of Calgary, Calgary, Canada. For more information on the symposium, please visit: www.incamresearch.ca.

KEYWORDS: IN-CAM research symposium

*Various authors of Symposium abstracts. For more information: www.incamresearch.ca.

Maximizing Chances, Minimizing Risks: Navigating Complementary and Alternative Medicine Decisions

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Background: The majority of women with breast cancer use complementary and alternative medicine (CAM). Limited research has been conducted, however, on the complexity of the CAM decision-making process. The purpose of this study was to understand how women with breast cancer make decisions about CAM, with the aim of developing a theory of CAM decision making that will assist healthcare providers in supporting patients in making informed CAM decisions.

Method: Using grounded theory methodology, 21 women with breast cancer who were CAM consumers took part in in-depth, open-ended interviews. Thematic and open coding was conducted, followed by a constant comparison of the data. Member and expert checking was used to validate the study findings.

Results: Following their cancer diagnosis, the women attempted to “maximize chances, minimize risk” by using CAM therapies. This process was influenced by prior CAM use, experiences with cancer, beliefs about healing and conventional medicine, information-seeking behaviours, and significant others. Women reported varying degrees of conflict, however, as they navigated the gap they perceived between conventional and CAM cancer care. The women responded with one of three distinct decision-making processes: “stepwise”, “conservative”, or “integrative”. These processes varied regarding how information was evaluated, the role of healthcare providers, and the goal of care. **Conclusions:** Women with breast cancer engage in different CAM decision-making processes in response to the lack of integrated healthcare services. The study implications include better prediction of CAM utilization across the cancer experience, improved CAM communication, and the development of appropriate CAM information resources.

Explaining Divergences in the Regulation of Dietary Supplement Health Claims: Regulatory Archetypes of Canada and USA

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Background: In the USA, Supreme Court decisions now require the FDA to approve health claims that include qualifying statements and disclaimers, such "This statement has not been evaluated by the FDA." Health Canada's regulations make no such provision, but instead admit "traditional" health claims. Both cases are a response to having to regulate health claims based on supportive, but inconclusive scientific evidence. To my knowledge, few if any studies have attributed these divergences to systematic differences in regulatory philosophy or intent. **Objective:** This paper aims to explain these differences in regulatory responses, as a function of consistency or coherence in the development and enforcement of regulations. In this sense, differences in regulatory responses can be understood as representative of different "regulatory archetypes." **Method:** I review the historical development of the FDA's and Health Canada's regulatory policy for dietary supplements health claims and analyze them with respect to regulatory artifices created by each agency, such as the different categories of efficacy claims, and the "standard of significant scientific agreement" employed by the FDA. **Findings/Conclusion:** Different archetypes of regulation identified in the analysis correspond to differing beliefs and social values with respect to fundamental questions such as the role of government agencies and the deference of agency discretion to ideals such as freedom of expression. A given archetype can be expected to maintain coherent regulatory formulae as new regulatory challenges emerge. These findings may be significant in light of recent initiatives to harmonize regulations across different jurisdictions.

Canadian Consumers' Perceptions of the Risk Information on the New Natural Health Product (NHP) Labels

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Background: The new Canadian federal natural health product (NHP) regulations came into law January 1, 2004. It is not clear how consumers will react to the new NHP labels including additional risk information. **Objectives:** To 1) Determine how consumers perceive the risks associated with using NHPs; 2) Explore how the information provided on labels as mandated by the NHP Regulations impacts consumers' perceptions of these risks; and 3) Investigate what other factors affect consumers' perceptions of the risk(s) associated with using NHPs. **Methods:** Data were collected through six focus groups held in Ontario between Nov. 2005 – Jan. 2006. Participants were asked to respond to two mock labels for the fictitious NHP "Saturnflower," one of which conformed to the old labelling standards, the other to the new labelling standards. Responses were transcribed and analyzed using interpretive content analysis. **Results:** Most participants were unaware of the new NHP regulations. Many, but not all, perceived little risk associated with NHPs. Consumers used many different sources of information and generally did not rely on the label to make product choices. Most liked the new labels (more information was generally considered better), but concerns about the cost, and potential for decreased choice and access to NHPs because of the new regulations were expressed. **Conclusions:** Consumers generally favour the increased amount of information on the new NHP labels, but it is unclear how important this will be in increasing informed decision-making given the wide variety of information about NHPs consumers are accessing to make product choices.

N-of-1 and Homeopathy: Bringing Research to the Clinic

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Background: As with many other complementary modalities, homeopathy uses clinical methods that involve individualized treatment. This makes the assessment of homeopathic treatments with standard randomized controlled trial (RCT) methodology challenging. **Objectives:** The objective of this research is to evaluate the feasibility of using N-of-1 methodology to assess classical homeopathy in an office-based setting. Attention Deficit Hyperactivity Disorder (ADHD) will be used as a sample medical condition. **Methods:** Medline and Embase were searched from the years 1996-September 2006 using the keywords homeopathy AND attention deficit hyperactivity disorder AND clinical trial OR N-of-1. Methodological information on: 1. N-of-1 trial design; 2. homeopathic RCT's, and; 3. ADHD trials using homeopathy was assessed. Classical homeopathy was examined as to the feasibility of maintaining model validity while rigorously assessing its effectiveness using the N-of-1 design. **Results:** Thirty-eight papers matched homeopathy and ADHD. Two RCT's on homeopathy and ADHD, and an N-of-1 trial evaluating methylphenidate for ADHD was identified. RCT design in homeopathy and ADHD has adopted methods that individualize patients within the study. N-of-1 trial design is applicable to stable chronic conditions with a fast return to symptoms after treatment is stopped. To maintain model validity for classical homeopathy, minor adaptations to the N-of-1 design are required depending on the medical condition. For ADHD, a variable washout period should be adopted to accommodate for a variety of remedy response rates. **Conclusions:** N-of-1 trial design has the potential to provide rigorous data for the treatment of ADHD using classical homeopathic techniques in a clinical setting. N-of-1 trials should be performed to further evaluate their clinical feasibility.

The Complementary and Alternative Medicine in Undergraduate Medical Education (CAM in UME) Project: Finding a Path in the Absence of Policy

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PURPOSE and IMPORTANCE: The CAM in UME Project aims to facilitate quality teaching of CAM-related issues in undergraduate medical education (UME). Its impetus and progress over the past four years is supported by a series of studies and workshops that focused on the role of, and need for CAM education in Canadian medical schools. The data from these studies were critical to guide a national team of educators to develop a viable CAM curriculum structure and supporting content materials. While the Project has the support of many key stakeholders, implementing CAM curriculum in UME is not mandated and is an individual school decision. The objective of this presentation is to examine potential 'policy related' avenues that may facilitate acceptance and integration of CAM content in UME. **DESCRIPTION OF THE INITIATIVE:** In order to be responsive to UME program needs across Canada and to lend credibility to our goals, our team identified three foundational themes in medical education: (1) Health Canada's principles of social accountability of medical schools, (2) the Royal College of Physicians and Surgeons of Canada's CanMEDS physician competency framework, and (3) the Medical Council of Canada examination objectives. **KEY FINDINGS:** Each area will be briefly described in the context of the CAM in UME Project. **CONCLUSIONS:** Society's increased demand for CAM has challenged our medical education system to uphold fundamental objectives in physician training such as patient-centred care and wellness. It is critical that we use existing written principles and objectives to bolster recognition of the Project as well as widespread dissemination of our curriculum-related resources.

Pilot Crossover Trial of Reiki vs. Rest for Treating Cancer-Related Fatigue

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Background and Objectives: Fatigue is an extremely common side effect during cancer treatment and recovery. Limited research has investigated strategies stemming from complementary and alternative medicine (CAM) to reduce cancer-related fatigue (CRF). This research examined the effects of Reiki, a type of energy touch therapy, on fatigue, pain, anxiety and overall quality of life. **Methods:** Counterbalanced crossover trial of two conditions: 1) Reiki: participants received Reiki for five consecutive daily sessions, followed by a one-week washout monitoring period of no treatments, then two additional Reiki sessions; 2) Rest: participants rested for approximately one hour each day for five consecutive days, followed by a one-week monitoring period of no scheduled resting. In both conditions, participants completed questionnaires investigating cancer related fatigue (FACT-F) and overall quality of life (FACT-G) before and after all Reiki or resting sessions. They also completed a visual analogue scale (ESAS) assessing daily tiredness, pain, and anxiety before and after each session of Reiki or rest. **Participants:** 16 patients (13 women) participated in the trial: 8 were randomized to each order of conditions (Reiki then Rest; Rest then Reiki). They were screened for fatigue on the ESAS tiredness item and those scoring above 3 on the 0-10 scale were eligible for the study. They were diagnosed with a variety of cancers, most commonly colorectal (62.5%) and were a median age of 59 years. **Results:** Fatigue on the FACT-F decreased within the Reiki condition ($p = .05$) over the course of all seven treatments. In addition, during the Reiki condition participants experienced significant improvements in quality of life (FACT-G) compared to during the resting condition ($p < .05$), particularly in the areas of functional, physical and emotional well-being. On daily assessments (ESAS) in the Reiki condition, pre-session 1 vs. post-session 5 scores indicated significant decreases in tiredness ($p < .001$), pain ($p < .005$) and anxiety ($p < .01$), which were not seen in the resting condition. **Conclusions:** Future research should further investigate the impact of Reiki using more highly controlled designs that include a sham Reiki condition and larger sample sizes.

Evidence-based Review of the Natural Health Product Milk Thistle (*Silybum marianum*)

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Background: There is a need to provide evidence-based information about complementary and alternative medicine (CAM) for healthcare professionals and the public. CAMline is a website (www.camline.ca) that provides free access to such information. Purpose: To gather information from various sources of literature and write an evidence-based review on the natural health product milk thistle (*Silybum marianum*) for CAMline. **Methods:** Textbooks and databases were used to find journal articles about milk thistle. The review was limited to English articles and abstracts in the primary literature, as well as summaries of non-English studies published in English secondary sources. Indications, adverse effects, and drug interactions were classified according to levels of evidence previously defined by CAMline. **Results:** Milk thistle was considered “possibly effective” and relatively safe for treatment of liver cirrhosis (one positive review article and two positive randomized controlled trials). “Possibly ineffective” indications included alcoholic hepatitis and viral hepatitis, including hepatitis B and C. Further research is required to determine its effectiveness for all other indications (e.g., hepatitis A, cancer prevention). Adverse effects included gastrointestinal disorders and pruritus. Drug interactions with milk thistle included hypoglycemic and psychotropic drugs from human case reports. A number of theoretical interactions were also found (e.g., acetaminophen, chemotherapy agents), however clinical studies are needed to confirm these suspected interactions. **Conclusions:** Milk thistle is possibly effective in treating liver cirrhosis and possibly ineffective in treating alcoholic and viral hepatitis. Further research is required to assess the efficacy of milk thistle for all other indications before it can be routinely recommended.

Clinical Case Reporting for Complementary and Alternative Health Care (CAHC) Practitioners: An Online Course

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Purpose: To develop an online course for CAHC practitioners in clinical case reporting. **Importance of the Problem:** It is important for CAHC practitioners to develop research capacity. For emerging professions case reports are a critical stepping stone to clinical trials. Few educational opportunities exist for practitioners to learn and apply evidence-informed, outcomes-based research methods to their practices. Case reporting is an important component of communication in most health professions. Yet, many CAM disciplines neither routinely publish nor educate practitioners to design and publish case reports. **Description of the Initiative:** To remedy this situation, the investigators designed and offered in three conference settings (2005-06), a three-hour workshop to convey to participants the history, purpose, methods and components of clinical case reports. Participants (80) in these workshops were also invited to participate in an evaluation of the workshop design. Analysis of the data uncovered the need for development of additional, flexible educational delivery models. **Key Findings:** Funded, in part, by an IN-CAM grant, the investigators are designing an eight-week, four unit, online course in clinical case report writing for CAHC practitioners: Unit 1 – Overview of Clinical Case Reports; Unit 2 – Finding and Critically Evaluating Case Reports; Unit 3 – Designing Case Reports; Unit 4 – Writing and Publishing Case Reports. **Conclusions:** Learning to design, conduct and publish case reports is believed to be a foundational component of building research capacity among CAHC practitioners, for the purpose of contributing to better care for clients/patients and increasing professional status and recognition. Asynchronous online delivery models allow for increased flexibility for learners.

Women's Experience of Massage Therapy during High Risk Pregnancy: A Qualitative Study

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Background: In Canada, pre-term birth occurs in 7.6% of all pregnancies and accounts for 60-80% of all perinatal mortality(1). Pre-term birth is increasing among industrial nations and is considered to be among the most significant human health issues(1). Partial or complete bed rest in hospital and/or at home is prescribed in 20 % of all pregnancies to reduce the risk of preterm birth in pregnant women with a variety of medical conditions 2,3). Pregnant women on partial or complete bed rest in hospital or at home can experience significant and lasting physical and psychosocial side-effects including: muscle dysfunction and pain, fatigue, and increased stress(4,5). Massage therapy has the potential to have a positive effect on the experience of high risk pregnant women on partial or complete bed rest in hospital or at home.(6,7). **Objectives:** To provide high risk, pregnant women in hospital or at home with massage therapy to obtain information from the experiences of women for the development of a clinical trial. **Methods:** Using qualitative methods, this study involves recruiting 6 women admitted to the high risk antenatal unit at Sunnybrook and Women's College Hospital. Two massages per week are provided in hospital or at home until delivery. At six weeks post-partum, the women will complete a semi-structured interview. All participants will also complete pre and post massage therapy session questionnaires: the Massage Therapy Satisfaction Questionnaire (based on the Measure Yourself Medical Outcome Profile or MYMOP) and the Arizona Integrative Outcomes Scale. **Results:** Recruitment and data collection is underway, analysis will be completed by October 31/06. **Conclusions:** TBA in November 2006.

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Prevalence of Traditional Chinese Medicine and Other Complementary/Alternative Medicine use Among Chinese Cancer Patients

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Background: Little is known about the use of complementary/alternative medicine (CAM), including traditional Chinese medicine (TCM) in ethnic populations with cancer living in Canada. **Objectives:** This study assessed the prevalence and predictors of TCM/CAM use in newly diagnosed Chinese cancer patients. **Methods:** A consecutive sample of newly diagnosed Chinese cancer patients treated at the British Columbia Cancer Agency was surveyed. During admission, study questionnaires were distributed along with other registration forms and returned in well-labeled boxes. A bilingual Chinese interpreter was available to answer any questions participants might have had. The 15-item questionnaire focused on TCM/CAM use, socio-demographics, and medical and cultural factors. **Results:** Ninety-one patients completed the questionnaire. The majority of respondents (90%) were born outside of Canada and 64% completed the questionnaire in Chinese. TCM/CAM was used by 44% of respondents. Herbal remedies, vitamins/minerals, and prayer were the most commonly used therapies. In the bivariate analysis, factors predicting TCM/CAM use were prior TCM/CAM use ($p < 0.001$), having received chemo/radiotherapy ($p = 0.021$), female sex ($p = 0.015$), immigrant status ($p = 0.040$), and reporting a non-official language most frequently used at home ($p = 0.018$). Multivariate analysis demonstrated that prior CAM use ($p < 0.001$), lower income ($p = 0.043$), and immigrant status ($p = 0.030$) predicted TCM/CAM use. **Conclusion:** TCM/CAM use in newly diagnosed Chinese cancer patients is common and results are comparable to previous studies in other populations. Healthcare practitioners must become aware of the widespread use of CAM and engage discussions about CAM use with their patients, especially those of a specific ethno-cultural group who may be less acculturated to Western society.

Multiple Sclerosis Pain and Acupuncture: A Review

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Background: There has been a steady increase in the use of Complementary and Alternative Medicine (CAM) internationally. A large percentage of individuals using CAM have one or more chronic diseases. Persons with Multiple Sclerosis (MS) are using CAM therapies for a variety of MS related symptoms. MS is a debilitating neuromuscular disorder with a reported high prevalence of unrelieved pain (approximately 50%-70%). Acupuncture is a recognized complementary therapy for the relief of pain. The purpose of this review was to investigate the use of acupuncture as a complementary approach in the management of pain in MS. **Methods:** The Medline, National Institutes of Health/National Centre for Complementary and Alternative Medicine, MS CAM, Pub Med and Cochrane Library databases were searched using the key words: Multiple Sclerosis, pain, acupuncture, complementary and alternative medicine. Criteria for inclusion in this review were: that the researchers had to have reported acupuncture as an independent modality, and report pain as an outcome measure. Only articles published in English were requested. Only two articles at the time of this review met the inclusion criteria. **Conclusions:** Research published in English on MS pain and acupuncture is almost non-existent. Some MS patients are reporting a reduction in pain from acupuncture. Methodological issues limit the clinical utility of the research finding in the review. More rigorous research is required to address disease related methodological challenges, the utilization and efficacy of acupuncture as a complementary intervention for the management of MS related pain.

The Professionalization of Herbal Medicine in Canada: A Case Study of Political and Institutional Opportunities and Challenges

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Background: Increasingly, complementary and alternative medicine (CAM) practitioners are seeking to professionalize vis-à-vis the attainment of self-regulatory status. In Canada, for example, “Traditional Chinese Medicine Herbalist” (TCM.H.) was recently recognized as a professional regulatory category. **Objectives:** To document the efforts of primarily “Western” herbalists to attain self-regulation, with a focus on the existing political and institutional opportunities and challenges that form the context of these efforts. **Methods:** Documents from professional associations, professions regulatory Colleges, provincial professions councils and the federal Natural Health Products Directorate (NHPD) were reviewed. Additionally, in-depth interviews were undertaken with (primarily Western) herbalists and a small number of representatives from other traditions practicing herbal medicine (e.g. TCM). Finally, existing empirical research was drawn on in an effort to contextualize the political and institutional developments discussed here. **Results:** Institutional influences such as the introduction of NHP regulations at the federal level, the regulation of TCM, and the introduction of umbrella professions regulatory frameworks at the provincial level (that permit overlapping scopes of practice) suggest a shift away from Western biomedicine as the exclusive basis of legitimacy and professionalization. While these developments do not diminish the political influence of Western biomedicine per se, they do create both new opportunities and challenges for herbalists seeking to professionalize. **Conclusion:** In summary, diversity (or at the very least, a non-Western or non-biomedically oriented scope of practice) does not necessarily constitute a barrier to professional recognition or regulation, given the existence of precedent-setting institutional arrangements at the federal and provincial levels of government.

An Enlightenment Scale

Hudoba P, Thompson L, Caire J, Chuck A, Hsu, S, Sha Zhi Gang
Sha Research Foundation

It is well-known that, during spiritual evolution, spiritual practitioners undergo profound changes in their mental, emotional and spiritual composition. These are described in the scriptures of various spiritual orientations in great detail. Successful spiritual practitioners dissolve their ego structure, develop profound empathy and compassion toward others, and wish to generously and selflessly serve humanity. This transformation is accompanied by profound inner joy and peace, by an increase of intelligence and wisdom, and by an increase in spiritual standing. Enlightenment is a state characterized by very specific changes in body, mind and soul as described in holy scriptures. Over several years, we have developed a Questionnaire to capture these changes. The sensitivity of this instrument was studied in a short double blind randomized study. Thirty-six spiritual practitioners of various orientations (Christian, Catholic, Jewish, Buddhist, Hindu) were randomized into two groups. Each group received a distance blessing from spiritual master Zhi Gang Sha in a blind fashion one week apart. All subjects completed self-assessment Questionnaires within two days before each blessing session and again one week after the second blessing session. Using psychometric analysis and reliability analysis of data from the study we were able to eliminate less sensitive questions and group the remaining questions into six coherent units: Body; Mind; Emotions; Wisdom (Intuition); Heart (Compassion); Soul. For each unit we obtained internal consistency of Cronbach's Alpha of more than 0.8, and as high as 0.95 in some. Detailed analysis of the data will be discussed during the presentation. The Institute of Soul Mind Body Medicine and Sha Research Foundation are co-sponsors of the study, which was conducted at San Francisco, California, USA. The study included subjects from both the USA and Canada.

A Balanced Mix of Outcome Scales for Low Back Pain Assessment

Hudoba P, Caire, J, Chuck A., Hsu, S, Sha Zhi Gang
Sha Research Foundation

Authors believe that in order to evaluate the overall effect of the treatment of back pain, specific and focused outcome measure instruments are not sufficient. Authors emphasize the need to measure not only pain, but also overall disruptions to general activities, normal work, mood and enjoyment of life, and economic and social changes. Therefore, a proper mix of scales covering various areas of patients' lives needs to be used. The research team has studied standard outcome measure instruments which have been routinely used in conventional medicine. After thorough review, a balanced mix of the most pertinent scales was developed. The scales selected for our study of low back pain cover the following areas: Character and intensity of the pain; Distribution of the pain; Length of time of the pain; Disability caused by the pain; Economic and social impact of the pain; Emotional impact of the pain. In this presentation, authors will discuss each selected scale separately, pointing out the pros and cons of each and the rationale for their utilization in the study. Researchers will also present the simple and efficient method they developed for collecting research data. The Institute of Soul Mind Body Medicine and Sha Research Foundation are the co-sponsors of the study, which is being conducted in San Francisco, California, USA. The study includes subjects from both the USA and Canada.

Expertise-based randomized controlled trials to assess spinal manipulation for low back pain? A systematic review of an innovative trial design

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Background: The randomized placebo-controlled trial (RCT) design is the gold standard for pharmaceutical research. However, this may not be an optimal design for non-pharmacological trials. For example, because it takes training and experience to develop expertise in spinal manipulation interventions, individual manual therapists tend to primarily use specific manipulative approaches for specific low back conditions. The restricted expertise that results can compromise the validity of conventional RCTs. An emerging trial design, the “expertise-based” RCT, randomizes participants to clinicians with expertise in intervention A or B. **Objectives:** 1) To determine the number of low back pain studies that have used an expert RCT design; 2) To extract the parameters around the characteristics of these trials. **Methods:** A comprehensive search of all relevant electronic databases (e.g., MEDLINE, Pedro, MANTIS, ICL) from inception to December 2005, and a grey literature search (e.g., reference lists, experts in the field) was conducted. Searches were screened and two reviewers independently applied eligibility criteria. Only trials of low back pain that randomized participants to clinicians with expertise in A (eg, activator technique), or clinicians with expertise in intervention B (eg, Maitland technique), in where clinicians performed only the intervention they are expert in, were included. **Results:** Our search yielded 4113 references and after screening, 166 articles were identified for collection. Of these, 102 were RCTs, yet none met our inclusion criteria. **Conclusions:** Use of expertise-based RCT design to evaluate spinal manipulation for low back pain is non-existent. The merits of this innovative design deserve full discussion before conventional RCTs continue.

Expertise-based randomized controlled trials to assess spinal manipulation for low back pain? A systematic review of an innovative trial design

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Probiotics to prevent pediatric antibiotic-associated diarrhea: A Cochrane review of explanatory and pragmatic clinical trials

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Background: Antibiotic treatment is known to disturb gastrointestinal microflora, resulting in a range of clinical symptoms, most notably, antibiotic-associated diarrhea (AAD). Meta-analysis data from pediatric clinical trials may help determine which probiotic strain(s) and dose(s) yield the most beneficial results in children. **Objectives:** To assess the efficacy and safety of probiotics (any specified strain or dose) for the prevention of antibiotic-associated diarrhea in children. **Methods:** A Cochrane systematic review and meta-analysis involving randomized controlled trials that compared probiotic treatment with placebo, standard care (eg, diosmectite), or no treatment control in children less than 19 years of age were included. **Results:** Ten studies were included (n=1986). The combined results using a per-protocol analysis reporting on the incidence of diarrhea, show significant results for the use of probiotics compared to placebo (RR 0.49; 95% CI 0.32, 0.74). In contrast, intention-to-treat analysis showed non-significant results overall (RR 1.09; 95% CI 0.70, 1.69). Subgroup analysis on five studies providing ≥ 5 (i.e. 5-40) billion colony forming units(CFU)/day showed strong evidence for the preventative effects of probiotics for AAD (RR 0.35; 95% CI 0.25, 0.47). No serious adverse events were reported. **Conclusions:** The potential protective effects of probiotics to prevent pediatric AAD do not withstand intention-to-treat analysis. Before routine use is recommended, further studies, with limited losses to follow-up are merited. Trials should involve probiotic strains and doses with the most promising evidence (e.g. Lactobacillus GG, or S. boulardii at 5 to 40 billion CFU/day). **Conflict of Interest:** BCJ has received study product from Culturelle Inc., the manufacturer of the probiotic - Lactobacillus GG, for evaluation in pediatric patients with irritable bowel syndrome.

Integrating Scar Massage into Burn Care Provided at an NGO Hospital in Cambodia

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St. John's Rehabilitation Hospital

Purpose: To evaluate the feasibility and potential for integrating scar massage into the post-operative care of burn survivors by introducing scar massage treatments and training local Cambodian health care workers in the scar massage protocol. **Importance of the problem:** It is widely recognized that post-operative burn rehabilitation is crucial and yet is severely lacking in Cambodia. Costs and training associated with technologically sophisticated medical devices and acceptance of western modalities makes it challenging to introduce certain interventions into the health care provision into a country like Cambodia. Massage exists in Cambodian culture, it is relatively easy and inexpensive to teach and learn, and it can be taught to health care workers, family members and patients. As such, scar massage (developed within a western context) may be an important modality used in the rehabilitation process of burn patients at this Cambodian facility. **Description of the initiative:** A Canadian burn scar massage therapist spent two months working daily at Children's Surgical Center (CSC) in 2005 with follow-up pending in 2006. Health care workers who worked with patients daily at CSC were identified by the Canadian therapist as the most suitable for training and to provide scar massage at CSC. An education package was developed for trainees by the therapist on-site (in English) based on experience and specific needs of the health care team at CSC. A formal (2hr) seminar was provided for medical staff about post-operative care and how scar massage was being integrated into the existing daily routines. **Results:** In 2005, two health care providers (one dressing nurse and one physical therapist) were trained in basic scar massage. Scar massage was incorporated into daily patient care during dressing changes and stretching exercises of 6 burn in-patients during the two-month project in 2005. Scar massage was also taught to family members (parents, children) and to patients as a self care tool. Scar massage integration into the daily routine was achieved by the end of the initial 8 weeks. **Conclusion:** Scar massage is an easily learned and transferable treatment technique. It is low cost and can be administered by health care workers and/or family members. Follow up in 2006 is planned to follow-up on the outcomes of the initial visit and to continue training.

Effects of Massage Therapy in Pain Management for Complex Trauma Patients Undergoing Long Term Rehabilitation at an Ontario-based Rehab Hospital: Four Case Studies

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Background: Patients with complex trauma or chronic pain are often prescribed high doses of narcotic pain medications for extended periods of time (6 months to 3 years), which have known negative side effects. Functionally, clients taking narcotics are often unable to drive, unable to operate industrial machinery, and report decreased memory and concentration. Massage Therapy (MT) is a common pain relief modality/therapy that is non-pharmacologic, non-invasive and with few negative side-effects. Research studies have quantified the effectiveness of Massage Therapy in pain reduction (low back, tension headaches, relief of trigger points). **Objective:** To examine the effectiveness of massage therapy in the pain management plan for patients with complex trauma injuries – amputees and motor vehicle accidents (MVA) - in a hospital based out-patient rehabilitation program. **Methods:** Four cases were studied: two MVA patients (one chronic, one acute pain) and two amputee patients with significant phantom pain. Pre and post treatment values for the Short Form McGill Pain Questionnaire (SF McGill), Pain Visual Analog Scale (PVAS) and the Arizona Integrative Outcomes Scale (AIOS) were collected and compared over a four week period. Qualitative pain reports pre and post treatment were documented and examined. **Results:** Pain levels post MT were globally lower than pre MT on both pain scales, and subjective intensity of pain was substantially decreased pre and post treatment. Statistical significance was intermittently achieved. Descriptions of phantom pain pre and post treatment were improved in terms of intensity and coping ability. Patient ratings on the AIOS globally improved; however, results did not always correlate with a change in pain levels and pain intensities documented. **Conclusions:** MT appears to be an effective and important component of the overall pain management strategy for complex trauma patients with sub-acute and chronic pain. In addition to decreasing physical sources of pain, MT also appears to decrease anxiety and stress, both psychological factors that have a strong effect on the intensity of pain experiences. Future research needs to be done to confirm the results of this case series in a larger sample and to quantify whether patients receiving massage intervention require fewer narcotic drugs or for a shorter period of time.

I-MED INDEX, an innovative universal outcomes measurement tool

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Purpose: The purpose of the I-MED Index was to provide a universal (i.e. any therapy or illness) outcomes measurement tool which pertained to a a wholistic paradigm of illness and wellness. **Importance of the problem:** It is proposed that virtually all physical illness is the manifestation of 'imbalances' at one or more 'levels' of the individual, including physical-biochemical-structural, energetic, mental-emotional, subconscious and spiritual or higher level. While many therapies are available from numerous paradigms to address symptoms, it is difficult to evaluate at what level they are effective and how that ultimately impacts the symptoms. **Description of the Initiative:** The I-MED index is developed initially as a program evaluation tool at IMI. **Key Findings:** To date, the tool has proven useful in identifying efficacy of approaches, programs and therapies and is being applied to further evaluative studies. **Conclusions:** The I-MED index shows promise as a universal outcomes evaluation for a plethora of therapies and illnesses.

Canadian and U.S. Pharmacists' Attitudes, Knowledge, and Professional Practice Behaviors toward Natural Health Products: A Systematic Review

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Background: Although natural health products (NHPs) are widely sold in pharmacies, the legal, ethical, and practice responsibilities of pharmacists with respect to these products have not been well defined. **Objective:** This systematic review of pharmacists' attitudes, knowledge, and professional practice behaviours toward NHPs is intended to inform pharmacy regulators' and educators' decision making around this topic. **Methods:** Eligible studies were identified through a systematic database search for all available years through to March 2006. Articles were analyzed for this review if they included survey data on Canadian or U.S. pharmacists' attitudes, knowledge, or professional practice behaviours toward NHPs published in 1990 or later. **Results:** Sixteen studies were included. Due to the heterogeneity of the data, it was not possible to draw a conclusion with respect to pharmacists' general attitudes toward NHPs. Approximately equal numbers of pharmacists report positive as well as negative attitudes about the safety and efficacy of NHPs. There is strong agreement among pharmacists for the need to have additional training on NHPs, increased regulation of NHPs, and quality information on NHPs. In addition, survey data indicate that pharmacists do not perceive their knowledge of NHPs to be adequate and that pharmacists do not routinely document, monitor, or inquire about patients' use of NHPs. **Conclusions:** Further research is needed to explore the factors that influence pharmacists' beliefs and attitudes about NHPs, to accurately evaluate pharmacists' knowledge of NHPs, and to uncover the reasons why pharmacists do not routinely document, monitor, or inquire about patients' use of NHPs.

The Use of Naturopathic Healthcare Services in Children under the Age of 15

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Background: In Canada, the use of CAM practitioners by adults and children has been on the rise. Naturopathic medicine is a primary care service outside conventional medicine. Little is known about the patients seen by naturopathic doctors. Given the universal health care system in Canada, we wanted to examine why parents are choosing naturopathic medicine for their children. **Objectives:** To assess 1) the sociodemographic background of children and their families; 2) the reasons for use; 3) whether naturopathic and conventional services were being combined; and 4) the characteristics of the naturopathic practice. **Methods:** A cross-sectional survey of parents / caretakers of children consulting naturopathic doctors in British Columbia, Alberta, and Ontario. **Results:** Ninety-eight completed questionnaires were analyzed. Children's age was 6 months to 14 years; 42 (42.9%) were female and 56 (57.1%) were male. Parents surveyed tended to be mothers (91.8%), were highly educated (57.2% university), had high income levels (51.0% had income >\$60,000) and also saw a naturopathic doctor (88.7%). About half of the families (53%) had partial extended health coverage for naturopathic medicine. Naturopathic medicine was used in children for various conditions, including allergies (63.2%), digestive problems (27.5%) and skin problems (19.4%), and for a variety of reasons, including using all possible options (97.9%) and having a different (more holistic) approach to care (96.9%). About a third of parents (34.7%) reported to combining naturopathic and conventional care for their children. **Conclusions:** Naturopathic medicine offers treatment for children with chronic or difficult to treat conditions.

Correlates Associated with ACS Patients' Cardiac Rehabilitation and/or Mind-Body Therapy Participation

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Background: Participation in cardiac rehabilitation (CR) is integral to secondary prevention after acute coronary syndrome (ACS); however adherence is low, particularly among women. CR and Mind-Body therapies (MBT) represent traditional and alternative components of secondary prevention, yet there is little understanding of the correlates of participation. Objective: To investigate the correlates of ACS patients' CR participation, MBT practice, both, versus neither activity. **Methods:** 661 consecutive ACS in-patients (75% response rate) were recruited from 3 hospitals in Ontario; 462 responded (81% retention rate) to a self-report, 18 month post-discharge survey. Participants were queried about CR attendance, MBT practice, socioeconomic status, anxiety and depression (HADS), quality of life (SF-12), functional status (DASI), illness perceptions (IPQ-R), social support (ESSI), and exercise barriers (EBBS). **Results:** 404 participants with complete data were classified into 4 groups: MBT (n=60; 15%), CR (n=113; 28%), both (n=60; 15%), and neither (n=171; 42%). In multivariate analyses significant correlates of MBT were being older (OR=1.06), greater anxiety (OR=1.19), and lower exercise barriers (OR=0.22). Correlates of CR included lower exercise barriers (OR=0.38) and higher social support (OR=1.06). Correlates of both included being female (OR=4.21) and having a post-graduate education (OR=3.81). When MBT was compared directly with CR, significant correlates of CR included being younger (OR=0.89), lower functional status (OR=0.94), anxiety (OR=0.84), and education level (OR=0.25). **Conclusion:** 15% of patients with ACS practice both MBT and CR during recovery, with women and more educated patients most likely to use both. Promoting MBT within CR may interest female, elderly and anxious patients.

An evidence-based review of the natural health product Saw Palmetto (*Serenoa repens*)

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During the past decade, there has been increasing interest in complementary and alternative medicine (CAM). The CAMline website (www.camline.ca) was developed to provide in-depth evidence-based reviews of natural health products to both healthcare professionals and consumers alike. Saw palmetto (*Serenoa repens*) is a natural health product with a long history of use in Europe; however, its safety and efficacy has not been systematically reviewed on CAMline. The purpose of this project was to write an evidence-based review on saw palmetto, with a focus on its efficacy in reported indications, potential drug interactions, and adverse effects. A MEDLINE search was conducted, and various textbooks and tertiary literature were reviewed. Quality of randomized controlled trials (RCTs) and levels of evidence were assessed using scales developed by CAMline. The current evidence suggests that saw palmetto is likely effective for the treatment of benign prostatic hyperplasia (BPH), but no clear evidence exists to support its effectiveness for other reported conditions. Overall, saw palmetto is considered to be a safe and well-tolerated herb. Gastrointestinal complaints are the most common adverse effects reported; however, co-administration with meals has been found to be able to reduce the severity of complaints. Theoretical drug interactions, such as those with α -blockers and androgenic drugs, have been identified for saw palmetto, but no actual cases in humans have been reported. In conclusion, saw palmetto appears to be a safe and likely effective treatment for BPH, but more research is required in order to assess its efficacy for other indications. This evidence-based review will be peer-reviewed, followed by online publication on the CAMline website.

Paradigm-Based Indicators for Assessing Traditional-Based Indigenous Health Services

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A qualitative field study of health service frameworks entitled "Indigenous theory for health: enhancing traditional-based Indigenous health services in Vancouver" (2005), resulted in detailed recommendations for the enhancement of traditional-based Indigenous health practices both within the mainstream, and outside of it. Amidst the implementation of these recommendations, demand for indicators for evaluating evidence-based practice, led to a questioning of paradigm-based outcomes. It is insufficient to assess the outcomes of one paradigm by applying the indicators of another paradigm (though these may add to knowledge generation). What are the indicators of efficacy or malpractice within Indigenous paradigms? What are the positive and negative outcomes of the absence and presence of traditional-based practices? Secondary analysis of the prior field study narratives, using thematic and quantitative coding and dialogue with practitioners and clients, reveals some preliminary avenues for examining "evidence" for traditional-based Indigenous health services, from within Indigenous paradigms.

Movement observation in children with developmental delays

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Background: Movement assessment is an important tool in diagnosis and intervention of children at risk for developmental delays. Research suggests that compensations in fundamental movement patterns impact a child's development. Most standardized assessment tools focus on task completion rather than on how the child moves. **Objective:** The main purpose of this study is to describe challenges of movement assessment in children under five years of age who have developmental delays. We aim to develop complementary assessment protocols and vocabulary that describe children's functional movement adaptability. **Methods:** Qualitative developmental descriptors from kinesiology, neurology, dance and somatic movement therapy contributed to the development of a movement observation tool. Data was collected by non-participatory observation and videotaping of twenty-five children during hospital clinic motor assessments and play sessions. The data was analyzed both quantitatively and qualitatively using artistic inquiry. **Results:** We found that the children with developmental delays were compromised in their midline organization and their ability to move in relationship to gravity. While observing, the same concepts supported us to maintain self-awareness and attunement. **Conclusion:** The basic concepts of midline and weight sensing are useful in the observation of children at risk for development delays. In order to observe quality of movement, and to respect the principle of meeting the child where they are, we as practitioners and researchers need to be aware of the same variables in ourselves. A multi-level approach to movement assessment entails measuring the process of movement and the range of the child's qualitative and functional movement choices.

A Home-based Spirituality Education Programme: Qualitative Exploration of Participants' Experiences

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Background: A growing body of research reports that spiritual well-being plays a significant role in mental wellness. Findings from a completed randomized controlled trial (RCT) indicate that a home-based, 8-week spirituality education program lowers mood disturbance and increases mental health related quality of life. In this qualitative exploration we set out to understand how participants perceived the program's impact. **Methods:** This descriptive, qualitative study employed face-to-face, in-depth interviews with thirteen individuals from Calgary, Canada. Participants were sampled from the study population of the previously conducted RCT with self-referred clients suffering from emotional distress. Interviews consisted of open-ended questions that focused on how the spirituality education programme may have affected mood. **Results:** Clients described how their mood and life changed throughout and following the spirituality education programme. The following six thematic categories emerged: 1. Expansion of Spiritual Beliefs; 2. Changed Life Perspectives; 3. Calmness/Mental Clarity; 4. Improved Mental Health; 5. Improved Relationships; 6. Renewed Physical Energy. Interviewees perceived expanded spiritual beliefs, a changed life perspective and calmness as the core changes that lead to improved interpersonal relationships, improved mental health and renewed physical energy. **Conclusion:** Our findings suggest that the spirituality education programme impacts mood by shifting perspectives of life situations, oneself and others and by expanding spiritual beliefs. Spiritual teachings and practices could be an innovative and valuable adjunct intervention to improve mood. **Acknowledgement:** We are grateful to the Alberta Medical Association, Alberta Health and Wellness and the George Family Foundation for their generous support.

The Living Well Lab: Establishing a community based research institute to assess the impact of complementary medicine on the quality of life and rehabilitation of persons living with HIV/AIDS

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Background: Current HIV research has identified that “living longer ≠ living better”. However, complementary therapies (CT) are becoming a pillar of the preventative and rehabilitative efforts for people living with HIV (PWA). A community-based research institute called the Living Well Lab (LWL) has been established at Friends For Life (FFL), a nonprofit wellness centre in Vancouver, BC that provides CT’s free of charge to over 1700 PWAs, to measure outcomes for 500 members. The LWL uses a participatory process to evaluate CT use at FFL. **Objectives:** The objective of the LWL is to explore, through a participatory, community-based process whether participation in FFL’s wellness program will reduce symptoms and/or improve health and quality of life for PWAs. In addition to allowing for ongoing evidence-based evaluation of CT services at FFL, a user-friendly database will provide PWAs with tools to self-monitor and track their wellness journey. **Methods:** The LWL has been modeled since its inception as a participatory model; spearheaded by a consortium of community and scientific members. A longitudinal, mixed methods approach will be used to measure health and quality of life-related outcomes and experiences for 500 of FFL’s new and existing HIV+ members. 500 self-referred participants will complete a series of outcome packages at five time points. 100 participants from this group will be interviewed about goal setting and lived experiences. **Results:** The LWL model and its acceptability will be described. As recruitment is not expected to begin until September, only descriptive information and process factors will be presented.

A Survey of Complementary Therapy Services in Canadian Palliative Care Settings

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Background: Patients with advanced illnesses, such as metastatic cancer or HIV/AIDS, choose to use or express interest in receiving complementary therapies (CTs). Very little is known about the availability and delivery of CTs in the various palliative care settings across Canada including frequency and types of therapies used, funding, and barriers to delivery of these therapies. **Objectives:** To obtain information on CT services offered by various palliative care settings (inpatient units, inpatient and outpatient hospices, outpatient pain and symptom clinics) across Canada. **Methods:** An 30 item electronic survey was emailed in March 2006 to palliative care service providers listed in the public directory of the Canadian Hospice Palliative Care Association. Survey items included whether CT services are provided and/or allowed, the types of CT services provided and/or allowed, percentage of patients receiving CTs, staff responsible for co-ordinating and delivering CTs, funding, and barriers to delivery of these therapies. **Results:** Of 122 potential responses, 74 surveys were completed. Eight (11%) of palliative care settings provide, 33 (45%) allow, 24 (32%) both provide and allow, and 9 (12%) neither provide nor allow CTs. The most commonly available therapies are music therapy (36/63, 57%), massage therapy (36/63, 57%), and therapeutic touch (30/63, 48%). Less than 25% of patients receive CTs in approximately half of the responding sites that provide or allow these therapies. Very few salaried staff provide CTs with volunteers being the main providers. Only 5% of the sites receive funding for CT services. The greatest obstacles to the delivery of CT services include lack of funding (67%), insufficient knowledge by staff of CTs (49%), and insufficient knowledge on how to develop a process to make a CT service or program work (44%). **Conclusions:** While many palliative care settings provide or allow CTs, delivery of this service is hampered by a lack of funding, staff providers, and limited staff knowledge of CTs and program development. Further educational, research, and policy initiatives in this area are required.

Buy the way: an exploration of products and fees advertised on chiropractic websites in Alberta

Page S

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Background: Chiropractic's success as a health care profession is evidenced in part by the rising number of practitioners. Paradoxically, this success may start to cost the profession, as the number of consumers may not be increasing proportionally. Fewer patients mean less income for practitioners. Some chiropractors are responding to these pressures by marketing health products, devices and services. **Objectives:** To describe the extent to which Alberta chiropractors with websites sold health products and the extent to which fee discounts/service inducements are advertised. **Methods:** Chiropractic websites in the province of Alberta were identified using the online Telus Business Finder cross-referenced with the Yellow Pages print directories. The websites were searched and an inventory of the health products for sale was recorded. Fee discounts and service inducements were also recorded. **Results:** 56 websites were identified and reviewed. Just over half of the chiropractic websites surveyed contained information on health products for sale. Orthotics were sold most often (N=29 practices; 51.8%), followed by pillows and supports (N=15; 26.8%), vitamins/nutritional supplements (N=15; 26.8%) and exercise/rehabilitation products (N=10; 17.9%). Nine practices (16.1%) offered some type of inducement to potential customers. These included discounts on treatment packages (N=2; 3.6%) free gait/posture analyses (N=2; 3.6%) and free general consultations with the chiropractors (N=3; 5.4%). **Conclusions:** The marketing of health care products and services by chiropractors in Alberta is common. Professional guidelines vary on the acceptability of these practices. Consumer and practitioner perspectives and practices regarding retailing need to be further examined.

Developing a full vertical CAHC Taxonomy using a Interaction/Wellness Paradigm

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Purpose: As other authors have indicated, a taxonomy of CAHC practices has an important purpose in understanding the relationship of the practices to and amongst each other, and for knowledge transfer to both health practitioners and CAHC consumers. Since 2001, the Association of Massage Therapists and Wholistic Practitioners (AMTWP) has been refining its full vertical and horizontal taxonomy system to provide a credentialing and educational framework. **Importance of the Problem:** To understand the relationship of CAHC practices, systems, and educational requirements/components, the inter-relationships amongst CAHC practices must be clearly understood. **Description of the Initiative:** The AMTWP system uses a practitioner/wholeness paradigm rather than allopathic paradigm. Thus, horizontally the modalities are defined by competency sets and the primary mode of interaction rather than by their therapeutic action. Vertically, knowledge extends from individual techniques and competencies through increasingly complex levels of organization to systems and Integrative Health Care. A fully-developed glossary supports the conceptualization and provides language clarity. **Key Findings:** The system is congruent, thorough, functional, and operational. It converses with identified modalities and theoretical structures of other taxonomy systems. The somatic versus non-somatic (body-mind) action difficulties of other systems are avoided, as they are secondary to the healing (modality-client) relationship. Assessment-only modalities are also included. **Conclusions:** While the conceptual theory of other taxonomies address the context of how CAHC modalities heal, methods of action are still debated, limiting their adoption. This taxonomy is direct, flexible, and works within the field ambiguities.

Music at a Time Like This

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Background: A hermeneutic-phenomenological qualitative inquiry of a music therapy support group for adult cancer patients explored the meaning of the experience from the participants' point of view. **Objectives:** The purpose was to gain an emic perspective of the experience with the aim of better understanding the meaning of music therapy for them. The distinction between emic and etic perspectives originating from linguistics now is used widely in sociology and anthropology to refer to accounts made from a stance indigenous or internal to a situation or language (emic perspective) and those made from a stance external to a situation or language, including the position of the observer or researcher (etic perspective). **Method:** Participants were self-recruited from hospital and community cancer facilities by means of an invitation flyer. The group met for two hours over eight consecutive weeks. No previous music experience was necessary. The person's desire for support of their cancer experience was the primary inclusion criteria. **Results:** Ten adults aged 24 to 72 participated. Cancer types and disease stages were not homogenous. The music-centred focus diminished differences of age, gender and disease. Participants experienced a profound, nonverbal connection to themselves, to each other, and connection to something larger—the music—beyond themselves. Creative self-expression through improvised music-making was particularly empowering and provided feelings of control. Positive effects of the group were reported to be long-lasting. **Conclusions:** The music therapy support group contributes a unique option for psycho/social/spiritual support of cancer patients. This model can be extrapolated to other clinical populations.

Vitamin E for improving lung function in people with cystic fibrosis

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Background: Cystic fibrosis (CF) is the most prevalent inherited disorder in the North American Caucasian population. Chronic progressive lung disease, the leading cause of morbidity and mortality in CF, is a combination of lowered host defence, inhibited airway clearance and oxidative stress. In addition, compromised antioxidant vitamin levels may contribute to free radical-induced damage to lung tissue. Vitamin E, a widely used natural health product, is an important exogenous antioxidant. It, along with fat and other fat-soluble vitamins, is malabsorbed in 85-90% of CF patients. A systematic review of this NHP in CF will allow us to either rationalize or de-rationalize its future use as an integrative treatment option. **Objective:** To determine the effect of vitamin E on pulmonary function in CF patients with chronic progressive lung disease. **Methods:** The following databases were searched using predefined search strategies: MEDLINE, PubMed, EMBASE, the Cochrane Controlled Trials Register (CCTR) and CINAHL. Studies were independently screened for inclusion/exclusion as well as abstracted by 2 reviewers. Quality was assessed using Jadad scores, allocation concealment and the Ottawa-Newcastle scale. **Results:** 320 abstracts were initially identified for relevance, 47 of which were initially selected for potential inclusion. Eight studies met the final inclusion criteria. **Conclusion:** At present, evidence from included studies is insufficient to demonstrate the use and effectiveness of vitamin E in improving lung disease in CF patients. Further studies of higher methodological quality (i.e. controlled trials) need to be conducted in order to actually determine if there is a definite clinical effect.

Antioxidant micronutrients for inflammation during lung disease in cystic fibrosis

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Background: Chronic progressive lung disease is the leading cause of morbidity and mortality in Cystic Fibrosis (CF). Sticky airway secretions characteristic of CF inhibit proper mucociliary clearance of pathogens. Clearance is further impaired by the induction of oxidative stress. Exogenous antioxidant micronutrients, common natural health products taken as dietary supplements, may be important in maintaining oxidant-antioxidant balance in the body. These micronutrients are malabsorbed in 85-90% of CF due to pancreatic insufficiency. **Objective:** To determine the effect of antioxidant micronutrient supplementation on antioxidant status and inflammatory markers in CF patients with lung disease. **Methods:** MEDLINE, PubMed, EMBASE, Cochrane CENTRAL, and CINAHL will be searched using a predefined search strategy. Prospective studies will be screened by two independent reviewers using the following inclusion criteria: controlled clinical trials; participants of any age/gender with CF, in any stage of lung disease; receiving any antioxidant supplementation (vitamin E, Vitamin C, beta-carotene, selenium). Quality will be assessed using the Jadad scale while allocation concealment will be assessed according to Schulz. Data will be abstracted by one reviewer and verified by a second onto pre-formulated paper extraction forms. Primary outcome measures will be recorded as a continuous variable and success/failure will be interpreted based on comparison to basal measurements and secondary outcomes. If only dichotomous outcomes are reported, they will be included and analyzed separately from the continuous measurements. The data will also be evaluated for the presence of publication bias using graphical and statistical methods. **Results and Conclusion:** Not available at this time.

Women's information preferences regarding CAM for menopausal symptoms

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Background: Research on the health benefits and risks of hormone therapy (HT) remains contradictory. As a result of conflicting information about HT women are seeking alternative options and many are considering CAM to help alleviate their symptoms. **Objectives:** This study of mid-life women aims to: 1) assess how women gather, evaluate and use information about CAM in managing menopausal symptoms, 2) determine the extent and priority of women's information needs, 3) ascertain how to effectively communicate information to women, and 4) develop reliable and valid information materials that will assist women make informed decisions. **Methods:** Data were gathered through in-depth, semi-structured interviews and questionnaires with women recruited by notices posted in a women's resource centre and in family physicians' offices as well as a notice in the women's resource centre's newsletter. **Results:** Information gathering, from multiple sources, was an ongoing process to evaluate the information and its sources using a systematic analytical approach. Women sought information about menopause and CAM including dosage and duration, and possible side effects or interactions, to validate symptoms and to assist with decision-making regarding treatment options. Preferred information sources included the women's resource centre, physician and practitioner's offices, and websites. Personal consultations with a practitioner and information that was concise and accessible in electronic or print format were highly valued. Brochures with information relevant to menopausal women are currently being developed. **Conclusion:** There is need for reliable, comprehensive information, in an easily understood format, about the risks and benefits of CAM for menopausal symptoms.

Why do children with juvenile idiopathic arthritis (JIA) use complementary and alternative health care (CAHC)?

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Background: Children with arthritis often use complementary and alternative health care but reasons for doing so are complex. These reasons may vary according to the characteristics of the individuals. **Objectives:** The aim was to explore the reasons why parents use these treatments for their child over a one-year period. We also wanted to understand if the children's and parents' characteristics influenced these reasons. **Methods:** A cohort of children with JIA (n=182, mean age: 10 years) who attended outpatient clinics were followed for up to two years. We evaluated the use of CAHC at three month intervals and demographic, disease-related and socio-economic variables. We also asked parents why they used CAHC for their child. **Results:** Use of CAHC ranged between 10% and 36% for the different three month intervals. The most cited reasons for using CAHC were for pain relief (60%), concerns about medications (52%), encouragement by a friend to use it (50%) and previous use of CAHC by the parents with positive results (33%). Dissatisfaction with conventional care was not a common reason for use of CAHC and 89% of those who used CAHC continued with their conventional treatment at the same time. Pain relief was a reason cited mostly by parents of older children (p<0.01) and concern about medications was cited by parents who had a child with a more severe disease (p<0.05). **Conclusions:** Parents used CAHC for their child for a variety of reasons, the main one being help with pain relief. The vast majority continued to follow conventional care at the same time as using CAHC. Factors associated with the main reasons for using CAHC were age of the child and severity of the disease. **Acknowledgement:** This research was funded by the Sick Kids Foundation, the Canadian Arthritis Network, the Canadian Institutes of Health Research and the Arthritis Society.

Hospital Based Massage: Integrating Somatic Practices in Acute Care Facilities

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Purpose: Practice guidelines are developed for Massage Therapy and related CAM practices in health care institutions. **Importance of Problem:** Use of massage in Canadian health care institutions has not demonstrated the same level of development, or provided the same opportunities for research as in the U.S., where a number of studies have been conducted on the effects of massage and related CAM practices in health care institutions, and where the use of massage therapy in hospitals has increased 30% in the last two years. **Description of the Initiative:** The Somatics Institute was invited to participate in a hospital massage outreach program through Edmonton's Capital Health Authority. The School identified the opportunity to address the following limitations to current massage therapy curriculum: 1) Experience working in health care teams, 2) Practical knowledge of medications, medical conditions and medical procedures relevant to massage therapy, 3) Development of documentation, treatment indications and contraindications relevant to acute care conditions. **Key Findings:** Students have demonstrated increased ability in the areas identified above, as well as the ability to integrate adjunct CAM treatment modalities into massage practice. Finally, a documentation process was developed that will form the foundation for future studies. **Conclusions:** On-going training in acute care settings has helped massage students gain practical experience with conditions, medical procedures and medications that students typically have little opportunity to work with. Additionally, program outcomes emphasized the need for further study of the appropriate use of adjunct CAM techniques in an integrated massage therapy practice.

Mindfulness-Based Stress Reduction and Blood Pressure in Women with Cancer

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Background: Reducing symptoms of stress and the risk of cardiovascular morbidity through the delivery of psychosocial interventions is of particular importance for women with cancer. **Objectives:** A waitlist-controlled trial was conducted to investigate the impact of an MBSR program on blood pressure (BP) and psychological functioning in women with cancer. **Methods:** Twenty nine women with a diagnosis of cancer (mostly breast) were recruited from the Tom Baker Cancer Centre. Participants were either registered for immediate MBSR participation (n=18), or were waiting for the next program (n=11). Resting blood pressure was assessed weekly at home over the 8-week study period in both groups. Psychological functioning was assessed via questionnaires before and after participation in the immediate MBSR program, or the 8-week waiting period. **Results:** For participants with relatively high levels of baseline systolic BP at entry to the study, participation in the MBSR program was associated with a significant decrease in resting systolic BP over the 8-weeks relative to the control group, $F(1,27) = 4.51, p < .05$. In addition, MBSR participation was associated with decreased self-reported symptoms of stress, $F(1,27) = 5.18, p < .05$, depression, $F(1,27) = 4.56, p < .05$, rumination, $F(1,27) = 4.77, p < .05$, and increased mindful attention-awareness, $F(1,27) = 10.02, p < .01$. **Conclusion:** This study is the first to demonstrate that the MBSR program may be efficacious in reducing resting BP. Consistent with previous research, psychological functioning improved for MBSR participants.

Surveys of CAM use in Cancer: A Conceptual Jungle

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Background: Over the past 20 years more than one hundred surveys of CAM use in cancer have been published. Such surveys are still being conducted. Are we still learning from them? Do they benefit patient care? **Objective:** To systematically review the extent of and reasons for CAM use, characteristics of CAM users, use of information sources, disclosure of CAM use to physicians and recommendations made by researchers to health care providers. **Methods:** A review of published surveys of CAM use conducted between 1994-2006, in English, using a structured questionnaire or interview guide. **Results:** Variation in definition of CAM used, rates of use and survey design characteristics is enormous. Characteristics of use, reasons for use, use of information sources and communication about CAM with physicians also vary greatly: 1) in terms of how they are assessed, and 2) in terms of results. Recommendations for health care providers continue to state that communication between physicians and patients need to be improved and that health care providers lack information about CAM. **Discussion:** The lack of a conceptual framework of CAM use and factors related to CAM use, and the lack of standardization in study methods and design has led to large volumes of information that have limited relevance and are of limited use in developing appropriate CAM services in cancer care.

Evaluating Clinical Outcomes of the Integration of Chiropractic in a Primary Care, Hospital Based Setting

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Background: Primary care is increasingly being delivered by teams of medical and CAM healthcare providers. Clinical outcomes data is necessary for understanding how such integrative healthcare teams evolve as well as for developing best practices. **Objectives:** The purpose of this project was to evaluate the clinical outcomes obtained from a chiropractic clinic (CC) integrated within the Family Medicine Unit at St. Michael's Hospital (SMH) in Toronto, Canada. **Methods:** An outcomes evaluation protocol was developed with involvement of all team members. The final version included standardized instruments to measure pain, disability, general health and pain coping. A patient satisfaction scale was also used. The protocol was delivered by clinic staff at the initial visit (following consent) and on the discharge visit. Data on compliance of the patients with the protocol and on change scores of the instruments themselves were calculated and reviewed descriptively. **Results:** 258 patients (99.6% of those requested) consented to participate in the outcomes evaluation. The age range of this sample was 20 years to 85 years, with 63% females. 258, or 100% provided initial outcomes; 55 provided patient satisfaction data while 55 provided discharge outcomes, to date. Change scores for the clinical outcomes were all positive; many exceeded the published values of minimum clinical importance. **Conclusion:** The data from this study provide indications of the success of the implementation of a clinical outcomes protocol as well of the changes in clinical outcomes obtained by patients managed within this integrated program.

Correlates of Natural Health Product Use for Osteoporosis

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Background: Natural health product use has been examined among several patient groups, but to date, none have examined NHP use specifically for osteoporosis. **Methods:** A cross-sectional survey was mailed to 2662 participants in the Canadian Multicentre Osteoporosis Study (CaMos). Eligible participants included those who had a diagnosis of osteoporosis, used medications or supplements to treat osteoporosis or a bone density measurement (BMD) indicative of osteoporosis or osteopenia. The survey included a checklist of specific NHPs, an open-ended section for additional NHPs and questions regarding use of pharmaceutical therapies for osteoporosis. Survey data were subsequently linked to sociodemographic and health-related variables from the CaMos database. Factors associated with use of NHPs for osteoporosis were examined using log binomial regression. **Results:** NHPs were used specifically for osteoporosis by 22.3% of the respondents (446/2002). NHP use was higher among participants who had been diagnosed with osteoporosis, used osteoporosis medication or reported knowing their BMD results were indicative of osteoporosis. Participants who had used 3 or more prescription medications or used supplements for prevention or treatment of osteoporosis at the CaMos 5-year follow-up also had a higher prevalence of NHP use. Women without osteoporosis were more likely than men to use an NHP for osteoporosis (prevalence ratio [PR]=1.83; 95% CI=1.34, 2.51), but this gender difference was diminished among participants who had osteoporosis (PR=1.18; 95% CI=0.80, 1.74). **Conclusion:** Clinicians should be aware that many patients are using NHPs for osteoporosis. This preliminary analysis suggests that some factors often associated with NHP use (i.e. gender) may not influence NHP use among those with an osteoporosis diagnosis.

Complementary and Alternative Medicine Decision-Making by Women with Fibromyalgia

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Background: CAM decision-making in women with Fibromyalgia Syndrome (FMS) is a complex issue which remains under explored. FMS is different from many other chronic conditions in that it is impossible to verify FMS using objective measures, its etiology remains unclear and an unequivocal treatment strategy does not exist (Asbring & Narvanen, 2002). CAM use may have potential risks; therefore more insight into CAM decision making processes must be gained (Rao et al., 1998). If dissatisfaction with conventional treatment emerges as a reason for CAM use, health care providers should be made aware of this. Much can be learned from FMS patients as they are substantial CAM users (Ernst, 2000). **Objectives:** To build a decision-making model based on the process that women with FMS go through when making the decision to use CAM. **Methods:** Grounded theory methodology was used for this study (Glaser & Strauss, 1967). Individual, in depth, semi structured interviews were conducted with 17 women diagnosed with FMS. Participants discussed their perceptions of CAM, how they approach CAM decision making and what their experiences are with CAM. The interview data was used to generate the emergent substantive theory. Also, the Fibromyalgia Impact Questionnaire (FIQ) was used to capture disease burden which provided the context in which decision-making takes place. **Results:** Participants went through 4 phases when making the decision to use CAM: 1) Establishing readiness, 2) Initiating FMS self management, 3) Getting organized, 4) Taking action. The core category was "Improving functional self". **Conclusions:** Understanding these phases will assist health care providers in giving tailored care specific to the syndrome's stages. By using the Andersen socio-behavioral framework the process of CAM utilization can be accurately captured (Andersen & Newman, 1973).

Reporting of Adverse Events Associated with Herbal Products

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Background: While many herbal products are relatively safe, they are pharmacologically active compounds with potential risks. Adverse event (AE) information collected by the current spontaneous reporting system suffers from severe under-reporting. In order to improve understanding of safety and risks of herbal products, it is necessary to investigate barriers to report, as well as behaviours after experiencing an AE. **Objectives:** The research question for the study is: What factors are associated with reporting of herbal product related AEs? The objectives of this study are to: 1. Understand and compare the perceptions of pharmacists and health food store personnel at the point-of-sale about safety, risks and incidence and reporting of AEs associated with herbal products (Phase 1); 2. Explore behaviours and factors associated with AE reporting for herbal products by consumers (Phase 2); 3. Investigate and compare responses from consumers that purchase their products at various locations (Phase 2). **Methods:** This is a qualitative study. In phase one, 10 health food store personnel and 10 pharmacists will be purposefully selected for interviews about if, when, where and why they report suspected AEs with herbal medicines. In phase two, consumers that have used an herbal product and experienced an AE in the last month, will be recruited. Upon consent, further information about their use of this product, experiences of AEs and perceptions of reporting AEs will be collected via in-person (or telephone if necessary) semi-structured interviews. **Results:** This presentation will present preliminary results from phase one. It is anticipated that 10 interviews will be completed and analyzed, with both health food store personnel and pharmacists. Key themes such as barriers to reporting and opinions about herbal product safety will be identified and explored qualitatively using quotations from the participants. Any quantitative information (such as demographic info) will be used for descriptive statistical purposes only. **Conclusions:** Conclusions will not be made until data collection has been completed. However, this project aims to improve current understanding of AE reporting associated with herbal products. It is anticipated that potential barriers to reporting will be identified to facilitate hypothesis generation about potential improvements to the current reporting system and possible needed changes to current Natural Health Product regulations.

Canadian Print Media Portrayals of Complementary and Alternative Medicine for Cancer: Prevalence and Characteristics

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Background: Many factors contribute to the high prevalence of complementary and alternative medicine (CAM) use by cancer patients, including disease related and sociodemographic characteristics, individual values and beliefs, and social and cultural forces. The mass media are a dominant cultural force that can (in)directly influence cancer patients' values and beliefs, and, not surprisingly, 1) many studies cite an increase in media reporting as a primary reason for the observed increase in CAM use, and 2) many cancer patients cite the media as a primary information source for CAM decision-making. Little is known, however, about this important information source. **Objectives:** To determine: 1) how often CAM use for cancer is reported in the Canadian print media; 2) what is reported; and 3) how it is reported. **Methods:** A content analysis of Canadian print media sources (Calgary Herald, Edmonton Journal, Globe and Mail, National Post, Chatelaine, Flare, Maclean's, Prevention, Time) published between 1990-2005 is being conducted. **Results:** This research is currently in progress. A total of 1,170 articles were identified: 987 from newspapers and 183 from magazines. An increase in reporting frequency was observed in the mid-1990's, with a peak in the late 1990's/early 2000's. Reporting frequency appears to have decreased in the early 2000's and to remain constant through 2005 at higher than mid-1990 levels. The most frequently referred to therapies are: natural health products, CAM therapies in general, nutrition (including special diets), meditation, spirituality (including prayer) and yoga. Trends in reporting frequency over time do not appear to differ by therapy type. Most commonly, this group of therapies is referred to as "alternative", or is not given a label; however, other less common adjectives include: complementary, holistic, natural, mind-body and unconventional. **Conclusions:** With a strong reliance on media information for CAM decision making, there is a large potential for cancer patients to be misinformed regarding CAM use. An understanding of the volume and content of media reports will help providers facilitate informed and appropriate decision-making. **Acknowledgements:** This research is supported by grants from the Canadian Institutes of Health Research, the Alberta Heritage Foundation for Medical Research and the Lotte & John Hecht Memorial Foundation.

Curing versus healing: The role of spirituality in treatment decision-making for men with prostate cancer who forgo conventional treatment and use CAM

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Background: The role of spirituality in the use of Complementary and Alternative (CAM) approaches by men with prostate cancer has hardly been explored. **Objective:** To explore the role of spirituality in cancer management by men with prostate cancer who forgo conventional treatment and use CAM. **Methods:** In-depth interviews were conducted at study entry (n=29). Themes were presented to participants in focus groups for verification. For a subset of participants (n=10) spirituality emerged as an important theme, therefore we conducted a secondary analysis of the interview data of these men to explore the role of spirituality in cancer management and decision-making. Follow-up interviews were conducted at 6,12,18,24 and 36 months. **Results:** Spirituality played a central role in decision-making and cancer management for a subset of participants. Some men viewed cancer as a spiritual journey and searched for meaning in their cancer experience. Others viewed cancer as a “gift” that had brought many blessings into their life. Participants expressed concern about how conventional treatments might interfere with their spiritual practice, which was important to coping with cancer. Some men used spiritual imagery to guide their treatment decision-making and healing. Having a cancer diagnosis influenced their spirituality by deepening spiritual practice, strengthening links with spiritual community and improving relationships. Two cases examples will be presented to illustrate the role of spirituality in treatment decision-making and healing over the three-year study. **Conclusions:** Spiritual beliefs and practices may play an important role in the formation of treatment choices. Further research and medical education is needed on spirituality and prostate cancer.

Recruitment Experience of a Clinical Trial on a Spirituality Teaching Program for Depression

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Background: It is a challenge to recruit patients suffering from depression for a clinical trial. **Objectives:** To describe the recruitment challenges, corresponding actions and resulting enrollment for a clinical trial using a Spirituality Teaching Program to treat unipolar major depression. **Methods:** At trial commencement in January 2005, recruitment was conducted by poster display in family physician clinics and through public service announcements. Information packages were sent to those inquiring about the study. In May 2005 recruitment procedures were modified: 1) the study poster was re-designed professionally; 2) phone coverage was arranged and study procedures were explained directly; 3) low cost advertisements and poster display were extended to community magazines, complementary and alternative medicine clinics and public display boards. Continuing poor accrual prompted further recruitment modifications in November 2005: 1) high cost advertisements were placed in newspapers and aired on radio stations; 2) study nurses became the initial patient contact so that information giving and eligibility screening could take place at the same time. **Results:** The table below shows the impact of the above procedures on cost and recruitment.

Recruitment Phases	Direct advertising cost	# of inquiries	# of clients screened	Screening rate	Enrollment	Intake rate
Jan. - Apr. 05 (4 months)	\$910	69	38	55.1%	5	7.2%
May - Oct. 05 (6 months)	\$3,170	230	140	60.9%	31	13.5%
Nov. 05 - Apr. 06 (6 months)	\$40,640	414	335	80.9%	68	16.4%

Conclusions: Professional advertising and a personal, client centered approach are necessary to achieve satisfactory trial recruitment of mental health clients.