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THE 3RD SICKKIDS FOUNDATION FORUM ON COMPLEMENTARY AND ALTERNATIVE HEALTH CARE AND PAEDIATRICS

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HOSTED BY

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ABSTRACTS

COMPLEMENTARY AND ALTERNATIVE HEALTH CARE AND PAEDIATRICS

SPEAKER PRESENTATIONS

1

Systematic reviews: current status and future developments

David Moher
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Systematic reviews are being published with increasing frequency. One recent estimate is that 2500 new systematic reviews are published annually. A factor contributing to this popularity is their centrality within the delivery of evidence based medicine: clinicians use them to inform treatment decisions; they are used as a starting point in the development of clinical practice guidelines; and some granting agencies are requiring them to support the rationale to support funding new research. Systematic reviews are most useful if they are of high quality and up to date.

This talk will present recent data on the quality of reporting systematic reviews, including those evaluating complementary and alternative medicine interventions, the authenticity of trials conducted in China, and the up to datedness of systematic reviews.

2

Paediatrics complementary and alternative medicine survey

Sunita Vohra, Edward Mills, Kim Humphreys, Tema Stein, Derek Stephens
Stollery Children's Hospital, Edmonton; The Hospital for Sick Children, Toronto
Funding Source: SickKids Foundation

Background: Canadian children are receiving complementary and alternative medical care in record numbers. There is little data regarding CAM practitioner knowledge, attitudes, and behaviour towards children in their practice.

Objective: To survey Ontario naturopaths, chiropractors, and osteopaths regarding their knowledge, attitudes and behaviour with respect to the children in their practice.

Methods: Three cross-sectional surveys were developed to assess Ontario naturopaths, chiropractors, and osteopaths. 1200 surveys (400 per practitioner group) were deployed using accepted survey methodology.

Results: Once the surveys are complete, we will have much more information about what conditions are commonly treated by various CAM professionals, what pediatric education they have received, and how they would manage children given particular clinical scenarios.

3

Complementary and alternative medicine use by children visiting a pediatric emergency department

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Funding Source: SickKids Foundation

Background: Most pediatric literature regarding Complementary and Alternative Medicine (CAM) is limited to the United-States and based on non-randomized self-administered questionnaires, with a low response and completion rate that have not taken into account the non-English speaking families. Literature regarding the use of CAM therapies by children in Canada is very limited.
Objectives: The purpose of this cross-sectional study was to determine the rate of CAM use by children visiting the Pediatric Emergency Department in a large tertiary center, to characterize the children and caregivers, including non-English speaking families and to determine if the visit to the Emergency Department is possibly caused by an adverse effect of CAM use or due to drug interactions with CAM.
Methods: We used quasi-randomization of the population studied, a sample size of over 1500 children, and we conducted face-to-face interviews with English and non-English speaking families.
Results: Determining the rate and type of CAM used can help verify the awareness of parents to safety, detect serious adverse effects and possible interactions between CAM and current conventional treatments. We will present the preliminary findings of this large-scale cross-sectional study and share some interesting findings on the rate and type of CAM used by children visiting our Emergency Department.

4

CAMline: Evidence-based reviews of the safety and efficacy of natural health products for children and expecting mothers

Heather Boon
University of Toronto, Toronto

CAMline (www.CAMline.ca) is a collaborative project whose main objectives are to: develop an evidence-based website for healthcare professionals (and the public); provide information on the safety and efficacy of CAM products, therapies and practitioners that is peer-reviewed, accessible, credible, practical, and objective; and provide a Canadian perspective on CAM. There are currently 35 natural health product reviews and 6 CAM therapy reviews online.
The distinct features of the website are: 1) the clinical focus of the information – it is practical, concise and applicable to the clinical practice of professionals or the self-management of consumers; 2) the Canadian focus of the material; and 3) the focus on providing children's doses and reporting what is known about safe use during pregnancy or lactation.
In this presentation, the content currently online will be reviewed highlighting how information relevant to children and expecting mothers is identified and presented on the web site.

5

Can maternal acupuncture for chemically dependent pregnant women reduce the severity of neonatal abstinence syndrome?-A randomized controlled trial

Patricia Janssen, Paul Thiessen, Ron Abrahams, Ann Kelly, Lorne Brown, Louise Demorest
University of British Columbia, Vancouver

Background: Approximately 6-10% of babies in Canada are exposed to illicit drugs in utero. As a consequence, these newborns experience painful withdrawal from narcotics or cocaine after birth.
Objectives: To compare among infants whose mothers have been randomized to receive either standard care (methadone maintenance) or standard care in combination with daily acupuncture treatments the following neonatal outcomes: days of morphine treatment, gestational age at birth, rates of intrauterine growth restriction, scores on a Neonatal Abstinence Syndrome Scale, rates of admission to a level II or level III nursery and length of stay, days to regain birthweight, and rates of apprehension by the Ministry of Children and Families prior to discharge from hospital.
Methods: The study is designed as a randomized controlled trial. Pregnant women on the Chemical Dependency Unit at BC Women's Hospital will be randomly assigned to have daily acupuncture.
Expected Results: We expect that babies born to mothers receiving acupuncture will have fewer and less severe symptoms of withdrawal because the acupuncture will alleviate mothers' cravings for street drugs and/or methadone. This in turn will assist women to reduce their dosage of maintenance methadone and prevent their return to use of street drugs.

6

Therapeutic touch for procedural pain in extremely premature newborns

Celeste Johnston, Julie Whitley, Bonnie Rich, Jennifer Cogan, Celine Goulet, Anne Monique Nuyt, Marsha Campbell-Yeo
McGill University, Montreal; McMaster University Health Centre, Hamilton; Ste Justine's Hospital, Montreal; IWK Health Centre, Halifax
Funding Source: SickKids Foundation

Background: Babies who are born very early must spend many weeks in the Neonatal Intensive Care Unit (NICU) where much of the care for them involves painful procedures such as heel sticks and needles. There are drugs and other means to decrease pain but these are either possibly dangerous or not appropriate for the tiniest babies. One promising therapy to try is called Therapeutic Touch.
Methods: In Therapeutic Touch (TT) a professional with special training in Energy Medicine will use his or her hands to assess the baby's energy field and then offer energy, as needed, to rebalance the field. The TT professional accesses and offers what is called "Universal Energy". Some studies have indicated that Therapeutic Touch is effective for decreasing pain in adults and one study with premature babies has shown that Therapeutic Touch promotes physiological stability and calmness in the baby, signs of comfort.
Results: The purpose of this study is to determine if Therapeutic Touch done by nurses with special training can decrease pain from a routine heelstick. Babies born at less than 28 weeks since conception will be invited to participate in the study. Each baby will have a fifty-fifty chance of receiving Therapeutic Touch or mimic Therapeutic Touch (nurse stands beside baby but does not actually do Therapeutic Touch) during the heelstick procedure which is being done to get blood for testing as part of usual care. How stable the babies' heart rate and body oxygen levels remain, how much the baby grimaces in pain, how stressed the baby is, and how quickly the baby recovers from the heelstick will tell us if the Therapeutic Touch works. Only the person doing the real or mimic Therapeutic Touch will know which group the baby is in.
Conclusion: The results could lead to safe pain management in tiny preemies.

7

The safety of St. John's wort in pregnancy

Myla Moretti, Gideon Koren
Motherisk Program, The Hospital for Sick Children, Toronto
Funding Source: SickKids Foundation

Background: Pregnant women with depression and anxiety are often afraid to take medicinal antidepressants such as the SSRIs, due to perceived fetal risk. St John's wort is by far the most commonly consumed natural health product for depression. It safety in pregnancy has not been reported previously.
Methods: We prospectively recruited pregnant women who called the Motherisk Program while consuming St John's, and matched them to two comparison groups: pregnant women with similar diagnoses taking an SSRI, and to women exposed to non teratogenic drugs. The mean daily dose of St. John's was 573+/-295mg and it was used for a mean of 7.2+/- 8.9 wks during the first and second trimesters. It was used for depression in half of the cases, for anxiety in a quarter, and for rarer reasons in the rest. A total of 40 cases per group were available for evaluation. The 3 groups were of similar maternal characteristics (age, weight, drinking, smoking, gravidity, parity, rates of spontaneous and therapeutic abortions).
Results: There was a significantly lower rate of live birth in the St John's group (75%) than among the other groups, due to a 25% rate of spontaneous abortions(p=0.003). There were no differences in gestational age, maternal weight gain, birth weight, rates of breast feeding, or major malformations (6.7%, 5% and 2.9% respectively).
Conclusions: St John's does not appear to increase the rates of major malformations. However, it should be used in caution in the first trimester, as it is associated with an increased risk of miscarriage.

8

Decision-making about complementary and alternative therapies for children and youth: legal, ethical and clinical issues

Joan M Gilmour, Christine Harrison, Sunita Vohra, Michael Cohen, Edward Mills
York University, The Hospital for Sick Children, Canadian College of Naturopathic Medicine, Toronto; University of Alberta, Edmonton; Harvard Medical School, Boston
Funding Source: SickKids Foundation

Background: This paper reports on a project undertaken by an interdisciplinary team with expertise in law, bioethics, paediatrics and epidemiology, in collaboration with the Canadian College of Naturopathic Medicine, to develop a policy framework and practical guidelines for consideration by health practitioners, parents and institutions faced with decision-making about use CAM practices and products to treat children.
Results: 1) While many of the same legal, ethical and clinical principles apply to CAM and conventional treatment, CAM raises some unique treatment and liability issues. 2) The "best interests of the child" that should guide decision-making may be far from clear or uncontested. Limited research on CAM's efficacy and safety, especially in children, means that decisions must frequently be made in conditions of uncertainty. Guidance and intervention principles are crucial. 3) Case scenarios can effectively act as a practical "anchor" to explore CAM policy issues when decision makers (parents, practitioners, hospitals and courts) are considering use of CAM therapies. 4) Using case scenarios, we illustrate the application of and shortcomings in existing guidance and intervention principles and outline preliminary recommendations for reform.
Conclusions: Issues raised by the scenarios include natural health product interactions with medication; physicians' referrals to CAM practitioners; parents who reject potentially life-saving medical treatment for CAM; parents who choose not to immunize their children; the 'mature minor' who prefers CAM to surgery against his parent's wishes; delay in medical diagnosis for a patient who is seeing a CAM practitioner and others. This presentation will focus on two: canvassing CAM alternatives when obtaining informed consent; and responding to patient / parental requests that hospitals allow or provide CAM on site.

9

The challenges of preparing a clinical trial application for the natural health product directorate of Health Canada: Suggestions for unassuming researchers

Sabine Moritz, Badri Rickhi
Canadian Institute for Natural and Integrative Medicine, Calgary
Funding Source: SickKids Foundation

Background: With the growing interest in studying natural health products, more academic researchers are faced with the task of having to prepare a Clinical Trial Application (CTA) for the Natural Health Product Directorate (NHPD) of Health Canada. This paper describes the application experience for a trial utilizing natural health products for childhood asthma.
Methods: The study the CTA was prepared for assesses whether using a naturopathic treatment regime will allow clinically stable asthmatic children to reduce their daily dosage of inhaled corticosteroids (ICS). The eight natural health products used in this trial are formulated as an orthomolecular (high dose) adjunct treatment for childhood asthma, for which no commercial preparation presently exists. The research team had no previous experience in preparing a CTA for NHPD and used the services of a consultant firm to assist with putting the application together.
Results: Preparation of the full CTA took approximately 18 months; this included:

1) a four months attempt of the research team to complete the necessary CTA documents without professional assistance;
2) two months to identify, interview and hire a consultant firm to assist with the CTA preparation;
3) seven months to identify NHPD licensed manufacturers willing to do small product runs and provide production and testing details for the CTA,
4) and seven months to prepare the full CTA including manufacturing details.

Review of the completed CTA by the NHPD took five months and ended with trial approval being granted. It is estimated that the process of obtaining NHPD trial approval added a total of $30,000 to the trial budget.
Conclusions: Obtaining approval for a clinical trial that involved natural health products can be costly and time consuming. To ease the application process for researchers in future a list of suggestions was compiled based on the trial teams' experiences. These suggestions will be shared in the presentation.

10

Is it possible to evaluate the practice of traditional medicines in Canada?

Jean-Paul Collet, Wanning Xu, Jun Chen, Michael Chung, Ruby Klink, Stanley Shapiro, Neil Macdonald, Stephen Lam
University of British Columbia, Children's & Women's Hospital, Vancouver; McGill University, Notre Dame Hospital, Montreal

Background: Traditional medicines are widely used by First Nations. Traditional Chinese medicine (TCM) is regulated (partially or totally) in several Canadian provinces and is used by an increasing number of patients. In a CIHR funded trial aimed at assessing the effects of TCM to improve the QoL of lung cancer patients, the TCM doctors could use 45 herbs that could be combined according to TCM diagnosis. We report in this abstract the experience of interacting with Natural Health Product Directorate (NHPD) in this context.

1) NHPD's forms have been developed to assess quality (good manufacturing practice), and safety (appropriate documentation) of finished products. Raw natural products that are used in various combinations, changing in time do not fit with this model.
2) NHPD rejected several products for their toxicity, while experienced TCM doctors were comfortable using them in a safe way at prescribed study doses. The fact that the same products are already being used in Canada raises the question of a double standard for assessing raw natural products' safety: the same products may be considered safe in real life and dangerous during a clinical trial.
3) One main safety concern: The possible varying expertise of different TCM practitioners was not addressed.

Conclusion: Our study was approved with significant distortions from traditional practice; this will impact generalization of our results. Overall, the experience suggests that our system is not yet well adapted to conduct this type of evaluation; hence, unfortunate need to wait longer for valid and relevant data.

POSTER PRESENTATIONS

1

The reliability of exercise testing in children with fibromyalgia and chronic musculoskeletal pain

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Funding Source: SickKids Foundation.

Background: No studies have looked at the reliability of exercise testing parameters in children with fibromyalgia (FM) or chronic musculoskeletal pain (CMP).

Objective: To determine the reliability of exercise testing in children with FM or CMP.

Methods: 29 children with FM or CMP, aged 8-18 years, participated in a randomized controlled trial comparing two 12-week exercise interventions. Each participant completed two exercise testing protocols 1-6 weeks apart. Each protocol included: 1) sub-maximal walking (VO_2sub-max), 2) peak aerobic capacity (VO_2peak), 3) anaerobic power at 90 rpm for 10 and 30 seconds, 4) body composition and, 5) tender point count. Test-retest reliability was assessed using the intra-class correlation coefficient ($ICC_{3,1}$) and Bland and Altman plots were used to determine limits of agreement (LOA).

Results: 26 participants completed all tests (female = 19), between 2005 - 2007. The mean values and standard deviation (SD) were as follows: age: 13.2 years (8-18; SD 2.4), height: 155 cm (127-171 cm; SD 12.0), weight: 55.2 kg (28-87.1 kg; SD 17.0), Tender point count: 10 points (0-18, SD 4.0) BMI: 22.6 (12.5-35.3; SD 5.7) and percent body fat: 26.1% (11-51.3%; SD 10.3). Some participants did not complete all tests due to fatigue or pain. For exercise testing parameters, the mean differences and standard deviation (SD) were as follows: VO_2submax: -0.01 L/min, SD 0.1 (Intraclass correlation coefficient (ICC): 0.90, Limits of agreement (LoA): ±0.14); VO_2peak: -0.04 L/min, SD 0.2 (ICC: 0.89, LoA: ±0.44); Power at 10 sec: 12.70, SD 56.1 (ICC: 0.89, LoA: ±112.2), and Power at 30 sec: -3.86, SD 52.9 (ICC: 0.90, LoA: ±105.8).

Conclusions: These results suggest almost perfect agreement of exercise testing in absolute VO_2submax, VO_2peak, and peak anaerobic power. Relative VO_2submax and VO_2peak agreement were substantial. Results suggest that exercise testing in children with FM and CMP is consistent and reliable.

2

Mindfulness-based stress reduction for urban youth: A pilot study

Erica M S Sibinga, Miriam Stewart, Trish Magyari, Cora G Welsh, Nancy Hutton, Jonathan M Ellen
Johns Hopkins Children's Center, Maryland, USA
Funding Source: Goldie Hawn Institute and Thomas Wilson Sanitarium for the Children of Baltimore City

Background: Mindfulness-based stress reduction (MBSR) has been shown to be beneficial for mental health and quality of life in heterogeneous adult populations. Few published studies exist in youth.

Objective: To investigate the feasibility and acceptability of MBSR for urban youth.

Methods: Participants were recruited from an outpatient clinic at a large urban hospital. The MBSR program was taught by an experienced MBSR instructor and consisted of eight weekly two-hour classes and a three-hour retreat. Feasibility was assessed through enrollment and session attendance. Acceptability was assessed through survey measures and individual interviews following program completion.

Results: In 2006, 27 patients 13-21 years old enrolled for two MBSR groups. Eighteen participants (67%) attended at least one MBSR session, of whom 15 (83% of attendees) attended five or more MBSR sessions and were considered completers. Analysis of interviews of completers identified themes related to program participation:

1. Decreased anger/negative emotions
2. Improved coping skills and decreased stress
3. Decreased arguments/aggression
4. Improved relationship with self and others
5. Improved physical well-being

After program completion, 14 of 15 participants reported having learned something of lasting value and all participants would recommend the program to a friend.

Conclusions: Our pilot study of MBSR for urban youth showed reasonable feasibility and significant acceptability, with considerable evidence that the MBSR group was deemed valuable by the participants. Given the small sample size, the data have limited power and generalizability. Nevertheless, these results suggest that further development and study of MBSR in this population are possible and warranted.

3

Safety and efficacy of commonly used herbs, vitamins and supplements during pregnancy and lactation – An evidence-based systematic review

Jean Jacques Dugoua, Edward Mills, Dan Perri, Gideon Koren

The Hospital for Sick Children, University of Toronto, The Canadian College of Naturopathic Medicine, Toronto; McMaster University, Hamilton

Background: There is a lack of basic knowledge on the part of both clinicians and patients as to the indications for use and safety of herbs used during pregnancy and lactation.

Objectives: To systematically review the literature for evidence on: 1) efficacy, 2) safety/harm during pregnancy and lactation, and 3) pharmacology of 60 commonly used herbs, 9 commonly used supplements and 6 commonly used vitamins.

Methods: We searched 7 electronic databases and compiled data according to the grade of evidence found.

Results: We found varying levels of evidence on clinical efficacy of herbs, supplements and vitamins for different medical conditions. We found fair level of evidence of harm during pregnancy for barberry, Oregon grape, goldenseal, blue cohosh, parsley, calamus, juniper, pennyroyal and deadly nightshade. We found very good to good levels of evidence of safety for garlic, horsechestnut seed extract, Echinacea, Korean ginseng, ginger, fish oils, *Lactobacillus sp*., St John's wort, vitamins (D, E, K, B6, folic acid).

Conclusions: A number of herbs show evidence of being effective aids for a number of conditions, however, some safety concerns are important to highlight for women considering the use of certain herbs during pregnancy and lactation.

4

Safety and efficacy of *Lactobacillus sp*. in pregnancy and lactation – A systematic review

Jean Jacques Dugoua, Edward Mills, Dan Perri, Gideon Koren

The Hospital for Sick Children, University of Toronto, The Canadian College of Naturopathic Medicine, Toronto; McMaster University, Hamilton

Funding Source: SickKids Foundation

Background: There is a lack of basic knowledge on the part of both clinicians and patients as to the indications for use and safety of *Lactobacillus sp*. used in pregnancy and lactation.

Objectives: To systematically review the literature for evidence of: 1) efficacy, 2) safety/harm during pregnancy and lactation, and 3) pharmacology of *Lactobacillus sp*.

Methods: We searched 7 electronic databases and compiled data according to the grade of evidence found.

Results: We found very strong and strong evidence of efficacy for diarrhea and atopic disease, respectively. We found strong evidence that intravaginal application of yogourt did not adversely affect the mother or fetus. We found strong evidence that the presence of *Lactobacillus sp*. in the vaginal flora may reduce the risk of preterm delivery. We found good evidence of mother-to-infant vertical transfer of Lactobacillus GG. We found very strong evidence of *Lactobacillus GG* being safe and effective at increasing the immunoprotective effect of breast milk.

Conclusions: Probiotic species show very strong evidence of effectiveness for various conditions. In pregnancy, yogourt appears to be safe and the presence of *Lactobacillus sp.* may reduce the risk of preterm delivery. In lactation, *Lactobacillus GG* appears to be safe and increase immune protection. Although there is strong evidence supporting the use of some probiotics in pregnancy and lactation, further characterization of individual strains and species is required before this group of natural health products (NHPs) can be safely recommended in pregnancy and lactation.

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5

The Mother Nature Network: Establishing a Canadian Network for Natural Health Products (NHP) during pregnancy and lactation

Jean-Jacques Dugoua, Gideon Koren, Laura Magee, Sunita Vohra, Doreen Matsui, Anick Bérard, Nick DeGroot, Edward Mills, Surinder Singh Sandu, Brad Johnson, Paul Saunders

The Hospital for Sick Children, University of Toronto, The Canadian College of Naturopathic Medicine, Toronto; University of British Columbia, Vancouver; University of Alberta, Edmonton; University of Western Ontario, London; University of Montreal, Montreal; Simon Fraser University, Burnaby

Funding Source: SickKids Foundation, Health Canada, Natural Health Products Directorate

Background: It has been estimated that between 7 and 55% of expectant mothers use herbal medicines, one type of NHP. Unfortunately, the safety and efficacy of natural health products (NHPs) during pregnancy and lactation is largely unknown. The Motherisk Program is the major Canadian group to counsel and monitor outcomes of women using medications or NHPs, or of women exposed to chemicals, radiation or infection during pregnancy and lactation.

Objective: To create a network for research on NHPs during pregnancy and lactation by forming longstanding collaborations among Canadian medical and complementary and alternative medicine (CAM) practitioners and scientists.

Methods: Mother-Nature Network members participated in three 2-day workshops and three conference calls throughout the length of this study. Each member was responsible to lead one theme and address the following: initiation, development, presentation and synthesis of comments of all members on the designated theme.

Results: An evidence-based consensus on fetal safety of selected NHP was undertaken. NHPs were prioritized as to their importance for future study. Areas for the prospective collection of data on NHP use in pregnancy and lactation were identified. A research and business plan was developed for the long-term sustainability of the Network.

Conclusions: The Mother-Nature Network is ideally situated to create a new climate in Canada, where data are collected and interpreted on the effects and safety of NHPs during pregnancy and lactation.

6

Expertise-based randomization methods for non-pharmacological trials of low back pain: A systematic review

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Funding Source: Duncan L. Gordon Research Fellowship, SickKids Foundation; Canadian Institutes of Health Research Fellowship Award and Canadian Institute of Health Research New Investigator Award.

Background: The randomized controlled trials (RCTs) have become the "gold standard" for evaluating the efficacy of clinical interventions. Patients are typically randomized according to intervention; however, when treatment is influenced by the skill-set of the provider it is advisable to randomize patients to therapists skilled in the procedures under evaluation. This is known as an expertise-based RCT.

Objectives: 1) To determine the number of RCTs that have compared the efficacy of different forms of SMT or acupuncture for LBP and have used an expertise-based RCT design; 2) To extract the parameters around the characteristics of these trials.

Methods: A comprehensive search of six relevant electronic databases (e.g. MEDLINE, EMBASE) from inception to December 2005, and a grey literature search (e.g. bibliographies, experts in the field) were conducted. Only trials of LBP that randomized participants to clinicians with expertise in A, or clinicians with expertise in intervention B, in where clinicians performed only the intervention they are expert in were included.

Results: One hundred and sixty-seven RCTs of acupuncture or spinal manipulation for LBP were identified, with 15 exploring the effect of competing techniques; however, none of these trials used an expertise-based design.

Conclusions: Trialists are not currently making use of expertise-based RCT design to evaluate acupuncture and spinal manipulation for LBP. This design offers a methodological safeguard against bias, referred to as "differential-expertise bias", when undertaking the design of studies to explore the relative efficacy of competing therapies that are likely to be influenced by clinicians' skills (e.g. acupuncture, spinal manipulation, physiotherapy).

7

A longitudinal analysis of types of complementary and alternative health care (CAHC) used by children with juvenile idiopathic arthritis (JIA)

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Funding Source: SickKids Foundation, Canadian Arthritis Network and the Canadian Institutes of Health Research and the Arthritis Society.

Background: The aims were to determine, over a one year period, which types of complementary and alternative health care (CAHC) were used by children with juvenile idiopathic arthritis (JIA), to evaluate which were the most beneficial from the parents' points of view, and to ascertain which factors were associated with perceived effectiveness of CAHC.

Methods: Children with JIA (n=182, mean age: 10.2 years at baseline) who attended out-patient clinics were followed for one year. We evaluated the types of CAHC used and its effectiveness from the parents' points of view at three-month intervals. We used regression models to determine whether socio-demographic, economic and disease-related factors were associated with perceived effectiveness of CAHC.

Results: Use of CAHC ranged between 10% and 24% over the different three month intervals. Types of CAHC that were mostly used in children with JIA were special diets, chiropractics and naturopathy. CAHC were considered at least moderately beneficial in 49% of the cases. CAHC that were considered the most beneficial according to parents were homeopathy, reflexology and osteopathy. Lower child health-related quality of life was the only factor associated with lower perceived effectiveness of CAHC ($p<0.05$).

Conclusions: Special diets were the most used CAHC in children with JIA. CAHC was perceived to be moderately beneficial by parents. Those whose children had a lower health-related quality of life perceived CAHC as being less effective.

8

Traditional Chinese medicinal herbs for the treatment of idiopathic chronic fatigue and chronic fatigue syndrome: A systematic review

Denise Adams, Taixiang Wu, Shusheng Tai, Natasha Wiebe, Sunita Vohra

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Funding Source: Salary support: SickKids Foundation, AHFMR, CARE Program, University of Alberta Evidence-based Practice Centre Project support: IN-CAM, University of Alberta, and Sichuan University Evidence-based Medicine and Clinical Epidemiology Center

Background: Chronic fatigue (CF) is increasingly common and is extremely difficult to treat using 'conventional' Western medicine. Traditional Chinese medicine (TCM) has a long history of treating CF with medicinal herbs, however, the quality and quantity of randomized clinical trials (RCTs) that have been conducted investigating this application is unknown. Reviews of Chinese journal publications have identified serious concerns regarding conduct and reporting of RCTs.

Objectives: 1) To examine the methodological rigour and quality of RCTs of TCM herbs for CF. 2) To assess these herbs for effectiveness and safety in treating CF.

Methods: Twelve English-language and three Chinese-language databases were searched. Potentially relevant references were assessed for the following inclusion criteria: 1) RCT; 2) CF diagnosis; 3) herbs used in TCM; 4) placebo, standard-of-care, or no-treatment controls; and 5) primary outcome of fatigue. Studies were assessed for randomization status through author interviews.

Results: Thirty-five trials, reported as RCTs, investigated TCM herbs for chronic fatigue syndrome; the majority were published in Chinese medical journals. Three studies were excluded for use of another TCM therapy as control and twenty-seven for lack of true randomization. Four studies are awaiting author contact. Full results will be presented May 2007.

Conclusions: Clinical studies of TCM herbs for chronic fatigue are being conducted. Methodological limitations, including lack of randomization, resulted in the exclusion of these studies from review. Trials investigating TCM herbs must be conducted with increased methodological rigour to be of value in evaluations.

9

Proliferative and toxic effects of *Ganoderma lucidum* on cells of the immune system

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Funding Source: SickKids Foundation and CIHR

Background: Ganoderma lucidum (Ling-zhi, Reishi mushroom) has been used in Traditional Chinese Medicine for over 5000 years. It has been suggested that the polysaccharide extract, PSGL, can be used as an adjunctive in paediatric patients undergoing chemotherapy to enhance the immune system and decrease the risk of infections. We evaluated the proliferative effects and toxicities of three different extracts: PSGL, GL, and Reishi.

Objective: The objective of these experiments was to determine the toxicity and proliferative effects of PSGL, GL, and Reishi in Jurkat E6.1 cells and LG2 cells, and in peripheral blood nuclear cells (PBMCs) obtained from healthy adults, healthy children and children undergoing chemotherapy.

Methods: A thiazolyl blue tetrazolium bromide (MTT) toxicity assay was used to measure percent cell viability as compared to control. Cells were incubated with PSGL, GL or Reishi ranging from 1 μg/mL to 200 μg/mL for 24 hours and 48 hours. After overnight incubation, cell viability was assessed using a spectrophotometer. Statistical significance was assessed using a one-way analysis of variance followed by a Dunnett multiple comparison test ($p<0.05$).

Results: In general, low doses (1 μg/mL – 10 μg/mL) of the three extracts resulted in increases in cell viability and higher doses (100 μg/mL - 200 μg/mL) resulted in decreases in cell viability in Jurkat E6.1 cells and LG2 cells. In PBMCs obtained from healthy subjects, the PSGL extract appears to have the most immunostimulatory effect; whereas, in PBMCs obtained from children undergoing chemotherapy, the Reishi extract appears to be more immunostimulatory.

Conclusion: Extracts of *Ganoderma lucidum* may enhance proliferation of cells of the immune system; however, these same extracts may also cause toxicity.

10

Effects of yoga on inner city children s well-being: A pilot study

Deborah L Berger, Ellen J Silver, Ruth E K Stein
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Background: Research on yoga suggests psychological and physical benefits, yet further investigation regarding its effects on children is needed.

Objective: Examine yoga's effects on inner-city children's well-being.

Methods: Pilot study comparing 4th and 5th graders at 2 Bronx after-school programs. One program offered yoga 1 hour/ week for 12 weeks (Y+) and other program did not (Y-). At Y+ and Y-, pre- and post-intervention emotional well-being was assessed by Harter s Global Self-Worth and Physical Appearance subscales and by 2 new scales: Perceptions of Physical Health and Yoga Teachings (Negative Behaviors, Positive Behaviors, Focusing/ Relaxation, Self-Control subscales). Flexibility (V-sit) and balance (1-leg standing) also were assessed. At Y+, children reported on yoga's effects and attendance was recorded.

Results: Consent and assent provided by ~ 40% of students. 39 Y+ and 32 Y- subjects were present at both pre and post-intervention. No differences in baseline demographics were found. Controlling for pre-intervention differences using ANCOVA, Y+ children had better post-intervention Negative Behaviors scores and 1-leg standing test scores than Y- ($p<.05$). Y+ children attended 68.5 % (mean) of classes; >50% reported improvements in directly targeted behaviors (e.g., strength, flexibility) but <50% reported improvements in non-directly targeted behaviors (e.g. homework, tests).

Conclusions: Children participating in yoga reported using fewer negative behaviors in response to stress and had better balance than a comparison group. Improvements in well-being, especially behaviors directly targeted by yoga, were reported. These results suggest a possible role of yoga as a preventive intervention and a means of improving children's perceived well-being.

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Dietary supplement policies in pediatric hospitals: Where are we today?

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Background: Little is known about the clinical practice and written policy regarding dietary supplement (DS) use in children's hospitals.

Methods: We conducted a cross-sectional survey on dietary supplement policies at 109 children's hospitals and related institutions in the US between March and September 2006.

Results: Of the 109 responding institutions, 65% described themselves as large tertiary care hospitals, 9% were large community hospitals and 25% were small, rural or other hospitals. Forty four percent reported having written policies on vitamins/minerals, herbs and other DS. Few hospitals had herbs (2%) and other dietary supplements (41%) on formulary. However, most allowed patients to use their home supply of DS under restricted use (81%) and 64% allow staff to make recommendations about HDS use. Nurses were most often required to store and administer the products (69%). Although most hospitals had a method for checking for drug/DS interactions, only 46% required documentation of drug/DS interaction check in patient documentation. Thirty two percent noted having pre-operative recommendations on dietary supplements prior to surgery.

Conclusion: Although 44% children's hospitals report having a policies on vitamins/minerals, herbs and other dietary supplements, there is a wide range in the quality of these policies. National guidelines for HDS policies and procedures need to be developed to ensure the safe use of HDS in children's hospitals.

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Knowledge, attitude and practice of Complementary and Alternative Medicine (CAM) among pediatric providers in the South Bronx, New York

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Background: The increase in CAM use in pediatric populations creates a need for effective physician-patient communication. Few studies currently address pediatric providers' attitudes, knowledge, and practices of CAM.

Objective: To assess 1) attitudes and practice patterns of CAM; 2) beliefs regarding patients CAM use; and 3) knowledge about and perceived need for CAM training among Pediatric Providers in the South Bronx

Methods: Self-administered questionnaires were collected from pediatric providers in the South Bronx, NY, from August to November 2006. The database of Pediatric providers comprised of online physician directories of managed care plans and included MD's, DO's and Nurse Practitioners in the fields of Pediatrics and Family Practice. The questionnaires included 21 items, asking about provider demographics, attitudes, practice patterns, beliefs and knowledge of CAM.

Result: Among the 70 providers identified 34 responded. 88% of respondents reported asking about CAM use always to seldom, while 12% never have. Among the providers who asked about CAM use more than half (59%) of providers recommend CAM, with 56% of them recommending it in conjunction with conventional medicine. The 3 CAM modalities most commonly asked about by the providers were dietary supplements (84%), herbal therapy (69%), and megavitamins (26%). However, most often recommended modalities were deep breathing exercises (16%), yoga/meditation (16%), prayer (12%), and massage (12%). The conditions where CAM is recommended most are behavioral/ psychiatric disorders (27%), asthma (23%), and colic (23%). No provider recommended CAM use for fever. Reasons cited for not recommending CAM are not enough knowledge (65%), adverse effects (36%), and not effective (18%). Most providers believe that less that 25% of patients use and discuss CAM. Over 70% believe that race/ethnicity, education levels and religion are the factors that most influence CAM use. 75% of providers consider their knowledge of CAM poor to fair. Half (50%) obtain their knowledge from personal experience, while 43% use the Internet, and 30% books. 82% of providers believe CAM should be part of residency training.

Conclusion: Most providers in the South Bronx report asking patients about CAM use and more than half recommend it. Lack of knowledge is the primary reason providers do not recommend CAM. Also, most providers believe a small percentage of patients use and discuss CAM. Most consider their knowledge fair to poor, and believe that CAM should be part of residency training.

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The rediction and revention of allergic disease in infants: N-3 PUFA supplementation

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Background: Alarming trends demonstrating the rise of allergic rhinitis and asthma have heightened the need for prophylactic immune modalities in complementary medicine that combat disease expression. In this study we have examined the potential role of N-3 polyunsaturated omega fatty acids (PUFA) as anti-inflammatory agents in allergy/ atopic asthma in infants, by measuring cord blood levels of immune progenitor cells. We have hypothesized that alteration in numbers, differentiation pattern, and cytokine receptor expression on CD34+ cord blood (CB) progenitors at birth might relate to the development of the allergic diathesis.

Methods: We performed CB analyses in a double-blind study of atopic, pregnant women randomized to supplemental fish oil (n=40) or olive oil (n=43) from 20 weeks gestation until delivery. At birth, CB mononuclear cells were analyzed phenotypically by flow cytometry and functionally by enumeration of cytokine stimulated colony forming units (CFU) for expression of CD34R, IL-5Rα, IL-3Rα and GM-CSFRα.

Results: Percentages of CB CD34+ cell numbers were found to be higher after N-3 PUFA than placebo ($p<0.003$). The number of IL-5 responsive Eo/B-CFU and the percentage of CD34+ cells positively predicted *atopic dermatitis* at one year of age. The number of IL-5 responsive Eo/B-CFU positively predicted *wheeze* at 1 year.

Conclusions: Thus, dietary N-3 PUFA supplementation during pregnancy in atopic mothers alters infant cord blood hemopoietic progenitors and their cytokine responsiveness, suggesting that *dysmature hemopoietic processes at birth may play a key role in the subsequent development of atopy.* Complementary approaches to targeting these processes may be helpful in the prevention and treatment of allergic disease.

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N-of-1 and homeopathy: Bringing research to the clinic

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Funding Source: SickKids Foundation Complementary and Alternative Health Care and Paediatrics Research Cross-Training Award

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. The following presentation and abstract were presented at: IN-CAM Symposium 2006, Nov. 4-5, Calgary.

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-l 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.

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The Self-Discovery Programme for children with emotional and behavioural difficulties in mainstream primary schools in the UK: A controlled study

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Funding Source: Chippenham Borough Lands Charity, England

Background: This study concerns the Self-Discovery Programme (SDP) designed for children with emotional and behavioural difficulties in mainstream schools. The aim of the SDP is to provide children with a range of practical relaxation skills (e.g. yoga, self and peer massage) that may enhance emotional well-being, increase self-awareness and promote self-regulatory behaviour.

Methods: Children (n=126) attending 4 primary schools were invited to take part in the SDP. Nineteen withdrew, thus 107 children aged 7 to 11 years participated in the SDP and the study. Data were collected by questionnaires completed by teachers at baseline (immediately before children commenced the SDP) and on completion of the SDP. Questionnaires included behavioural profiles and the Strength and Difficulties Questionnaire. On receipt of the baseline questionnaire children were placed into the Intervention (53) or Control (54) Group.

Results: Compared to the control group, children in the intervention group had significant improvements in mean scores on communication with teachers (p=0.001) and contribution to class (p=0.001). For the intervention group there was a trend toward better mean scores on self-confidence, social confidence with teachers and peers and improved eye contact. There were also improvements in the total difficulties score for the intervention group. At follow-up, greater percentages of children exhibited self talk, enhanced listening skills, increased attention span and use of massage techniques.

Conclusions: The SDP appears to have been a useful intervention for this group of children. Further studies using a larger sample appear warranted.

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An animal model of middle ear infection

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Funding Source: Supported by the SickKids Foundation: CAM 05-331R

Background: Middle ear infection (otitis media) is a common childhood disease that has experienced a steady rise over the last 10 years. The widespread use of antibiotics in the treatment of this disease has caused several strains of bacteria to become resistant to medication. This is a major concern to health care providers especially since the occurrence of middle ear infection in children is now about 44%.

Objective: The purpose of this study was to develop an animal model of otitis media for subsequent studies on the effect of homeopathic remedies on this disease process.

Methods: Two groups of Sprague Dawley rats (one, 175g-200g – group a and the other, 85g-100g – group b) were anesthetized. In group a, the middle ear bulla was exposed and an opening made through its inferior surface. The auditory tube was blocked through this opening, bacteria was introduced into the bulla and the opening closed with Duralay. In group b, the bacterial inoculate was introduced into the middle ear by an injection through the tympanic membrane. Hearing tests were performed before and one week after surgical intervention (group a), or before and one week after trans-tympanic membrane inoculation (group b).

Results / Conclusions: In both situations hearing was diminished after one week, and there were no apparent morphological changes in the structures of the middle ear. However, group b appears to be a better model for pursuing long term studies as they relate to middle ear infection in children.

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Relevance of a hypnotic relaxation intervention for paediatric cancer patients undergoing numerous painful procedures

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Funding Source: This pilot study is funded by The Chaire Lucie et André Chagnon pour l'enseignement d'une approche intégrée en prévention, Université Laval.

Background: Hypnosis in combination with local analgesia has been shown helpful in reducing pain and anxiety in paediatric cancer patients undergoing repeated painful procedures. In our milieu, intra-venous conscious sedation analgesia is routinely administered for these procedures. In these conditions, this study evaluates if the adjunct of a hypnotic relaxation intervention to sedation-analgesia is still relevant to facilitate completion of these procedures.

Objective: To quantify pain and anxiety levels in cancer children (6-16 years) undergoing a lumbar puncture (LP) or a bone marrow aspiration/ biopsy (BMA/B) under light to moderate sedation-analgesia using midazolam and/or ketamine and/or fentanyl.

Methods: Children's fear and pain levels were assessed before and during each procedure concomitantly by the children, the parents and the physician who administered the medication using a 6-point Facial Pain Scale and a visual analog scale, higher scores representing more intense pain or fear. Parents also assessed their own anxiety at the same time points

Results: On a 3 month period 12/14 children (mean age±SD: 9.0±2.9 years) completed the study evaluations (2 study refusals). In the 3 minute pre-sedation period, children's fear was evaluated at 3.6 ±2.8 by the children themselves, 5.4±2.9 by the parents and 4.3±2.8 by the physician (mean±SD). Parents assessed their own anxiety at 5.9±2.7. During the first needle puncture under sedation/analgesia, parents evaluated their own anxiety at 5.9±3.6. On average, parents assessed higher levels for their child's fear (4.4±3.9) and pain (3.8±3.6) in contrast with physician evaluations of children's fear (2.1±2.6) and pain (1.8±2.3). At the end of the procedure, children have retrospectively evaluated fear at 2.8±3.5 and pain at 1.9±3.0 during the needle puncture. Ten parents (83%) will agree to participate to a future study evaluating hypnosis for pain and anxiety.

Conclusion: A hypnotic relaxation in adjunct with conscious sedation analgesia could be helpful for reducing child's anticipatory pain before the cancer procedures. These results suggest that this intervention should include the parents to help them coping with their anxiety during procedures. More data are collected to evaluate pain and anxiety across repetition of procedures under sedation.

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Antioxidant micronutrients for oxidative and inflammatory stress in cystic fibrosis lung disease

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Funding Source: Trainee grant from the Department of Pediatrics, University of Alberta, and Complementary and Alternative Health Care & Pediatric Masters Scholarship from the SickKids Foundation.

Background: The leading cause of morbidity and mortality in Cystic Fibrosis (CF) is chronic progressive lung disease. Airway infection leads to progressive damage of the lung tissue, due in part to oxidative stress. Further, the body's antioxidants are depleted in conditions of acute oxidative stress. Supplementation of exogenous antioxidant micronutrients (vitamin E, vitamin C, β-carotene and selenium) may help in maintaining an oxidant-antioxidant balance. Current literature suggests that a relationship between oxidative status and lung function exists, often using oxidative and inflammatory markers as surrogate outcomes. A Cochrane Systematic Review (SR) will synthesize existing knowledge of the effect of antioxidant micronutrients on oxidative and inflammatory stress in CF patients.

Methods: Five major electronic databases have been searched using a predefined search strategy. Primary outcomes are lung function and quality of life. Secondary outcomes include measures of oxidative stress and inflammation. Screening, data-extraction and quality assessment (using Jadad and allocation concealment) will be conducted independently by two reviewers. Meta-analysis and sensitivity analysis may be performed and if so, subgrouped by sole antioxidant supplementation versus antioxidants with concurrent treatment.

Results: Six-hundred and five articles were identified and have been screened for potential inclusion. The full-texts of 42 articles are currently being screened for final inclusion.

Conclusions: While routine supplementation of fat-soluble vitamins addresses deficiencies in CF, the effect of antioxidant micronutrients, some of which are fat-soluble vitamins (E and β-carotene) is still unclear. As such, the synthesis of literature on the effect of antioxidant micronutrients for lung disease in CF will provide an indication of relevance of which antioxidants, if any, are promising adjunct therapies.

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Ginger inhibits acetylcholine-induced airway contraction and Ca^{2+} oscillations in murine lung slices

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Background: Asthma is a chronic childhood disease characterized by inflammation and hypersensitivity of airway smooth muscle cells to different spasmogens. The past decade has seen an increased use of herbal treatments all over the world for many chronic illnesses. Ginger is a common food plant that has been used for centuries in respiratory illnesses in children. In spite of this popularity, there is hardly any study justifying its use in such conditions.

Methods / Results: In this study, we report the airway relaxing activity of ginger in murine lung slices. Mice were sacrificed and the lungs were filled with agarose to stiffen the soft tissues. Lungs were then removed, cooled and after acquiring single lobes, 120 µm slices were prepared. These were loaded with a Ca^{2+}-sensitive dye fluo-4 for fluorescence studies. Airway contraction, recorded via phase-contrast and confocal microscopy, was induced with acetylcholine (ACh) while the effect of ginger (70% methanolic extract) was initially recorded in the absence and then upon ACh-induced contractions. Verapamil was used as a standard Ca^{2+} channel blocker. ACh (10 µM) exhibited airway contraction along with Ca^{2+} oscillations (in smooth muscle cells) seen as a decrease in airway width and increase in fluorescence respectively. Ginger (0.03-0.3 mg/ml) showed no effect on the naïve airways but when it was given 30 min prior to ACh administration, the ACh-induced contraction and Ca^{2+} oscillations were significantly reduced. Similarly, verapamil (1 µM) also inhibited the agonist-induced airway contraction and Ca^{2+} oscillations, indicating a similarity in the modes of action.

Conclusions: This shows that ginger inhibits airway contraction and the associated Ca^{2+} oscillations thus reiterating the effectiveness of this age-old herb in respiratory illnesses.

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Parent-delivered massage in paediatric oncology

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Funding Source: SickKids Foundation National Grants Program - Complementary and Alternative Health Care and Child and Youth Health Grants Competition

Background: In Canadian children aged 0-19, the number of new cancer cases from 1997-2001 was on average 1,285 children per year for a total of 6,427 children over a five year period. Individual and family responses to a child's or adolescent's cancer diagnosis and treatment include psychological, sociocultural and biological dimensions. Parents of children with cancer can experience severe emotional distress including anxiety and depression. Parents require support and skills to reduce their own anxiety and distress and to help alleviate suffering in their children.

Objectives: Phase I: To develop a standardized educational program, for hospital and home use, in parent-delivered massage therapy for children with cancer and evaluate its usability and learner satisfaction. Phase II: To test the feasibility of the educational intervention in parent-delivered massage for children undergoing treatment for cancer at a paediatric oncology centre to guide sample size estimation for a future randomized trial. *Research Question* – Phase I: How do parents of children with cancer rate a parent-delivered MT educational program for usability and satisfaction? Phase II: Does MT, provided by parents to their child with cancer, (1) reduce anxiety and reduce other symptoms for the child? (2) reduce anxiety, depression and parenting stress in the parent?

Methods: This is a two-phase research project using both quantitative and qualitative methods: phase I: development of a standardized educational intervention on video/DVD (Montreal and Toronto) to teach parents how to massage their child with cancer; phase II: test the feasibility of the developed intervention with children with cancer and their parents using a parallel-group, randomized trial on parent-administered massage therapy versus wait-list control. A total of 24 parents and their children with cancer who are under the care of the paediatric oncology units at the Stollery Children's Hospital (Edmonton) will be recruited.

Expected Results: It is hypothesized that this research on an educational program in parent-delivered massage therapy will directly improve the lives of children with cancer and their parents.

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