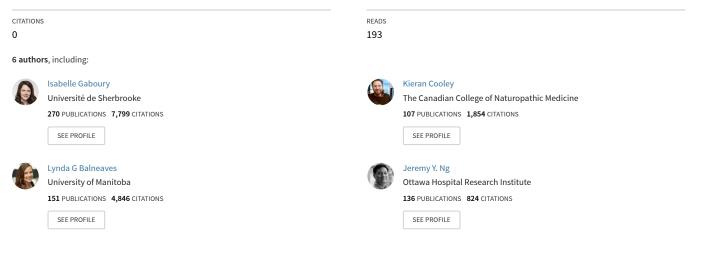
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2018 INCAM Research Symposium: Complementary and Integrative Medicine Research in an Era of Skepticism

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Abstracts

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2018 INCAM Research Symposium: Complementary and Integrative Medicine Research in an Era of Skepticism

Hotel LeCrystal, Montreal, Québec, Canada, 9-10 November 2018

Abstract: The following are abstracts of research presentations given at the 10th INCAM Research Symposium. The theme for this year's conference was "Complementary and Integrative Medicine Research in an Era of Skepticism" which was held on November 9-10, 2018 at the Hotel LeCrystal in Montreal, Québec, Canada. The abstracts are grouped under the categories of oral or poster presentation based on how they were presented at the Symposium. For more information, please visit: http://www.iscmr.org/content/incam/canadian-chapter-incam.

Keywords: complementary and alternative medicine, integrative health care and medicine, conference abstracts, professional practice gaps, research

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ORAL PRESENTATIONS

Naturopathy Special Interest Group (N-SIG) research capacity and needs assessment survey

Monique Aucoin (1), Kieran Cooley (1,2,3), Christopher Knee (4), Teresa Tsui (1), Diane Grondin (5)

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Background: Despite recent shifts in regulation and recognition of the role that naturopathy plays in healthcare delivery in Canada, comparatively little research has been conducted regarding individuals who conduct naturopathy-related research. A survey was undertaken in order to better understand the needs and capacity of these individuals to conduct more research.

Methods: The Naturopathy Special Interest Group (N-SIG) of the Interdisciplinary Network of Complementary and Alternative Medicine Researchers (INCAM) created an initial survey (2014; n=58). Results were analyzed, presented and discussed at a facilitated needs assessment workshop and used to inform the re-design and distribution for the survey. This study received approval and oversight from the Research Ethics Board of the Canadian College of Naturopathic Medicine.

Results: The survey was completed by 201 individuals (approximately 5-10% of all naturopathic doctors and naturopathy researchers in Canada). The majority (70%) had no peer-reviewed publication experience; however, 63% reported having published in a non-peer-reviewed medium. Respondents reported differing levels of confidence in completing various components of a research project. Frequently selected obstacles included lack of time due to professional and personal obligations, as well as insufficient training, funding and mentorship. The greatest identified needs for participation in research were mentorship/support, access to a wider degree of scientific journals and targeted funding opportunities for CAM research.

Conclusion: Overall, the results of this survey suggest that there is interest in further conducting naturopathy-related research. There are individuals who are already involved and have expressed skills in the area of evidence-based medicine. Mentorship, research training, resources and critical appraisal and writing skills may be important leverage points. Findings from this investigation will be used to inform an agenda for naturopathy-related research and activities of the N-SIG with respect to enhancing research capacity.

Diet and psychosis: A scoping review

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Introduction: Schizophrenia spectrum disorders (SSD) represent a cluster of severe mental illnesses. Diet has been identified as a modifiable risk factor and opportunity for intervention in many physical illnesses and more recently in mental illnesses such as unipolar depression; however, no dietary guidelines exist for patients with SSD. **Objectives:** This review sought to systematically scope the existing literature in order to identify nutritional interventions for prevention or treatment of mental health symptoms in SSD as well as gaps and opportunities for further research.

Methods: The review followed established methodological approaches for scoping reviews including an extensive a priori search strategy and duplicate screening. Because of the large volume of results, an online program (Abstrackr) was used for screening and tagging. Data was extracted based on the dietary constituent and analyzed.

Results: Of 55 330 results identified by the search, 822 studies met the criteria for inclusion. Observational evidence shows a connection between the presence of psychotic disorders and poorer quality dietary patterns, higher intake of refined carbohydrates and lower intake of fibre, omega-3 and omega-6 fatty acids, vegetables and fruit, and certain vitamins and minerals. Evidence illustrates a role of food allergy and sensitivity as well as microbiome composition and specific phytonutrients. Experimental studies have demonstrated benefit using healthy diet patterns and specific vitamins, minerals and amino acids.

Conclusion: Overall, these findings were consistent with many other bodies of knowledge about healthy dietary patterns. Many limitations exist related to design of the individual studies and the ability to extrapolate the results of studies using dietary supplements to dietary interventions (food). Dietary recommendations are presented as well as recommendations for further research including more prospective observational studies and intervention studies that modify diet constituents or entire dietary patterns with statistical power to detect mental health outcomes.

Nursing policies and regulations in the era of medical cannabis

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Background: Since 2001, medical cannabis has been legal in Canada. In 2016, the federal regulations expanded medical cannabis authorization to nurse practitioners (NPs), and nurses are increasingly caring for patients using medical cannabis. Whether nursing policies and regulations have kept up-to-date with this evolving field is uncertain. **Objectives:** The objectives of this study were to: 1) summarize existing nursing policies in Canada related to medical cannabis; and 2) explore the perspective of nursing regulatory bodies regarding practice and policy issues related to medical cannabis. **Methods:** Using a mixed-method approach, a national environmental scan of nursing policies was undertaken and 11 practice consultants were interviewed about current and pending medical cannabis policies, challenges nurses faced related to medical cannabis, and implications of legalized non-medical cannabis on nursing.

Results: 63% of nursing regulatory bodies had policies or statements related to medical cannabis, the majority of which focused on administration. Only Ontario allowed NPs to authorize medical cannabis to eligible patients; however, institutional policies were given precedent. Much confusion existed regarding the role of nurses in authorizing, administering and handling cannabis across practice settings. Lack of practice guidelines, ambiguity in federal regulations, impending legalization of non-medical cannabis, personal bias, and occupational health issues were perceived to be barriers to the incorporation of medical cannabis within nursing practice in Canada.

Conclusion: Study findings highlight the importance of harmonizing federal, provincial/territorial and institutional policies regarding the role of nurses in the authorization and administration of medical cannabis. Including cannabis within undergraduate and continuing education nursing programs will be essential if Canadian nurses are to provide safe and informed care related to medical cannabis.

A description of the professional identity of massage therapist in Ontario

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Background: The absence of a strong professional identity, either at the level of the profession or individual, leaves healthcare practitioners at risk of role blurring, ethical distress and burnout. Massage therapists have been described as having a feeble professional identity; the description of which is not clearly articulated in the literature. The communication of a common professional identity for massage therapists is needed to clarify the values and beliefs that underpin massage therapists' thinking, actions, and interactions. To explore this, an exploratory sequential mixed methods study was conducted, the results of the qualitative strand are reported here. Objectives: The qualitative strand sought to answer, "How do registered massage therapists in Ontario describe their professional identity?" **Methods:** Qualitative description was used to explore the research question. The population of interest was registered massage therapists (RMTs) in Ontario. To gain understanding of a diverse group of RMTs, maximize variation sampling on predetermined criteria was used. Data were collected using semi-structured interviews. Data collection and analysis occurred simultaneously. The three-step process of qualitative content analysis was undertaken by two of the researchers. **Results:** Participants described six themes related to their professional identity. These were: passion as professional motivation, confidence and competence, the therapeutic relationship, individualized care, patient empowerment and role recognition. Their identity is one of a healthcare provider who may not always feel respected as such. Conclusion: The next phase of this research is to create a questionnaire based on these results to be distributed to a larger sample of RMTs in Ontario. The objective is to explore whether there are factors that clearly effect the perceived professional identity within the profession. Once the second phase, or the quantitative strand, of the study is completed, both the qualitative and quantitative data will be analyzed to describe the

professional identity of massage therapists in Ontario.

A scan of the Canadian massage therapy education environment

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Background: Massage therapy (MT) education in Canada is undergoing a period of rapid change in response to regulatory requirements, evidence informed practice, and student, patient, and insurer expectations. This is reflected in the recent development of a programmatic accrediting organization, entry-to-practice competencies, and regulation of MT in two additional provinces.

Objectives: The purpose of the study was to identify the current state of MT education in Canada, the challenges facing education programs, how programs are adapting to address these challenges and to identify recommendations to inform curriculum development, education standards and practices.

Methods: Interviews were conducted to gain insight into stakeholder perspectives regarding MT education. Purposive maximum variation sampling was used to obtain a range of perspectives. Potential informants were identified through an internet search and by program representatives. Telephone interviews were recorded and transcribed. The transcripts were coded using each participant statement as a unit of analysis. Data reconstruction was completed by developing major themes, highlighting findings, and conclusions.

Results: Twenty-one massage therapists participated from six provinces. MT education was described as being "in flux," "at a crossroads," and "all over the map". Major challenges included: an inconsistent description of foundational knowledge, variation in educator training and resources, uneasy educator-regulator relationships, curriculum gaps, teaching today's learner, research for practice, and the need for networking. Some innovations mentioned were the application of inter-jurisdictional competencies, instructor training, integration of research, peer mentorship, program delivery models, and interdisciplinary faculty. Recommendations suggested included program standardization, evidence informed practice and pedagogy integration, inter-disciplinary, intra-professional and inter-institutional collaboration, and educator-regulator communication.

Conclusion: Participants indicated the national MT education landscape is diverse with significant differences between programs. However, many shared similar challenges and recommendations. Additional research is needed to explore the effects accreditation and best practices to address perceived challenges with this study for comparison.

Can lateral epicondylitis be relief by osteopathic treatments targeting tensions from the thoracic region? Results of a case study

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Background: Lateral epicondylitis (LE) is a musculoskeletal disorder causing pain in the lateral aspect of the elbow. This pain associated with a reduction in grip strength can limit the activities of daily life or sport performance. It becomes difficult to perform various activities such as turning a door handle, opening a jar, shaking hands, carrying groceries or lifting a cup of coffee. Few studies have examined the effects of osteopathic treatments in cases of chronic LE that have not been completely relieved by conventional treatment in physiotherapy.

Objectives: The objective of this case study is to determine whether LE that has been present for at least 6 months may be relief by osteopathic treatment of tensions coming from the thoracic region.

Methods: The case study was conducted on a subject suffering from chronic LE of the left elbow for 6 months and having previously received 4 treatments in physiotherapy. To alleviate the pain at the elbow, 4 osteopathic treatments have been applied. Measurements included: grip strength (dynamometer), strength of the extensor muscles of the wrist (muscle strength grading scale), range of motion of the elbow (goniometer), global pain and pain on palpation around the lateral epicondyle (visual analog scale) and special tests (Cozen, Mills and Maudlsey) for the diagnosis of LE. The evaluation was done before and after each treatment.

Results: The first treatment involving the correction of cranial dysfunctions did not significantly improve the patient's signs and symptoms. The two following treatments, addressing thoracic dysfunctions, yielded significant improvement in grip strength (from 23.3kg to 29.3kg), active (130° to 142°) and passive (133° to 145°) range of motion and global (7/10 to 4/10) and palpation (8/10 to 5/10) pain tests of the left elbow. The last treatment, involving mainly the normalization of the thoracic diaphragm muscle, the pelvic diaphragm and the cranial diaphragm, completely eliminated the patient's symptoms at the elbow.

Conclusion: The findings indicated that LE present for 6 months may have been maintained by tensions coming from the thoracic region. Osteopathic treatment addressing those tensions has completely relief chronic LE pain in this case.

Effect of global osteopathic treatment on functional mobility in the parkinsonian patient: A quasi-experimental study

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Background: Modifications in posture, gait and overall functional mobility are observed with Parkinson's disease progression. Some studies have reported that an osteopathic treatment focused on the musculoskeletal or cranial systems can produce a significant improvement in motor function and gait in this patient population. However, functional aspect of mobility received little attention despite the fact it is an important issue for Parkinsonians.

Objectives: Evaluate the effect of global osteopathic treatment on functional mobility in patients with Parkinson's disease.

Methods: Twenty patients diagnosed with Parkinson's disease (Heohn and Yahr stages I to IV) participated in this quasi-experimental time-series study. Functional mobility was assessed 1) twice using the Timed Up and Go test (TUG) during the first three weeks of the study before treatment was introduced, 2) before and after each of three osteopathic treatments carried out at one-week intervals and 3) at one and three weeks after the end of the treatment period. Osteopathic treatments were specifically adjusted to the persons' needs assessed during the initial evaluation and included musculoskeletal, craniosacral and visceral manipulations. An analysis of variance was used to assess evolution of functional mobility over time.

Results: Functional mobility was stable across baseline measurements taken prior to treatment. A significant improvement in functional mobility reflected by an increased speed in execution of the TUG was observed with time (p=0.001). Bonferroni post-hoc test showed that the changes were significant when the baseline results of the week preceding the introduction of treatment were compared to the results from the week which followed the treatment period (p=0.05). No significant improvement was observed when comparing the results of the TUG before and after each osteopathic treatment. **Conclusion:** These data suggest that three global osteopathic treatments can improve functional mobility of patients with Parkinson's disease. More research is needed to confirm these results.

Cannabinoids use in critically ill ventilated patients: A qualitative study using Q-methodology

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Background: Critically ill ventilated patients are often treated with continuous infusions of opioids and/or benzodiazepines in the Intensive Care Unit (ICU) to decrease pain and anxiety. Nevertheless, administration of these drugs has been associated with unintended consequences such as delirium and post-traumatic stress disorder (PTSD), and may potentially lead to addiction. Cannabinoid-based therapy has been effectively used to alleviate pain, anxiety and manage PTSD among patients in other settings with potentially fewer side effects. Despite this potential, the use of cannabinoids as an alternative to conventional medications is not without resistance, stigma or challenges from various perspectives or systems (i.e. infrastructure, regulation).

Objectives: To explore the acceptability of using cannabinoid therapy among former ICU patients, family members, ICU healthcare providers, and administrators.

Methods: A study using Q-methodology is currently in process to elicit the latent opinions of all relevant stakeholders. Q-methodology is frequently used in the process of healthcare implementation as a valid qualitative and quantitative research method for systematic exploration and description of the range of viewpoints about a topic. Our team started by creating a focused research statement and set of subjective statements presented to study subjects (Concourse). Responses to this set of statements were then condensed to a smaller subset (Q-sampling) through critical team discourse. A convenience participant sample ($n\sim30$) representing each stakeholder group will be recruited to sort through the Q-sample (Q-sort). Each participant will be asked to rank the statements according to their own subjective opinions.

Results: Q-factor analysis will identify patterns of subjectivity among responses by calculating the correlation coefficients between Q-sorts to identify common viewpoints. Final results will be available for presentation.

Conclusion: This study will generate a foundation of knowledge essential to planning feasible, high-quality clinical research evaluating the safety and effectiveness of cannabinoids in this setting.

Does integrative medicine approach reduce prescribed opioid use/dose for chronic pain? A systematic literature review

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Background: Chronic pain (CP) continues to be one of the most challenging health problems worldwide. Many patients with CP have been increasingly prescribed opioids leading to "Opioid Crises". Currently, many CP patients are using integrative medicine (IM) approaches either as adjunctive or alternatives to pharmacological treatments to alleviate their pain. Yet many IM options have often faced opposition by many claiming limited evidence to support the effectiveness of these approaches.

Objectives: This systematic literature review aims to explore the true effectiveness of IM to reduce or cease opioid use and reduce pain.

Methods: An online search of MEDLINE, Embase, CINAHL, PubMed supp. and Allied and Complementary Medicine Database (AMED) for studies published in English from inception until February 15th, 2018 was conducted. Our eligibility criteria included studies assessing the impact of using IM therapies on opioid use among CP patients. Cochrane risk of bias tools were employed to assess study quality.

Results: The electronic search yielded 5162 citations. De-duplication and screening of titles and abstracts resulted in 73 citations selected for full-text review. Twenty-one studies met all eligibility criteria and underwent data extraction; 9 studies were RCTs, 6 were observational, and 6 were retrospective chart reviews. The majority of studies showed that opioid use was reduced significantly after using IM. The cognitive-behavioral model was among the most commonly investigated approaches in reducing opioid use followed by cannabinoids and acupuncture. The majority of the studies had limitations with sample size, blinding, randomization and study designs.

Conclusion: There is a small, but defined body of literature demonstrating positive preliminary evidence that IM approaches can help in reducing opioid use. As the opioid crisis continues to grow, it's vital that clinicians and patients be adequately informed regarding the evidence and opportunities for IM approaches to help patients with CP.

Risky enough to regulate? The profession of homeopathy in Ontario, Canada

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Background: In 2015, the province of Ontario, Canada became the first industrializedworld jurisdiction to regulate lay homeopaths. Protecting the public from harm is the primary principle around which Ontario's Health Ministry frames decisions as to whether to regulate particular occupational groups; and lobbying practitioners had successfully argued that the practice of homeopathy can indeed carry considerable risk. Homeopathy, however, involves treatment with substances so highly diluted that - in most cases - no trace of the original material remains, raising questions as to how significant the associated risks may be.

Objectives: To investigate: a) the range of homeopathic practitioner views as to homeopathy's safety; and b) the regulatory ramifications of such perspectives. **Methods:** Critical thematic analysis of safety-related perspectives expressed in semi-structured interviews with newly-registered Ontario homeopaths (n=14).

Results: The homeopaths interviewed universally agreed that there was little to no risk of direct physical harm from the practice of homeopathy. Echoing paradigmatic tenets from the historical homeopathic literature, however, a majority among them characterized homeopathic remedies as having the potential to cause an unpleasant (but not dangerous) aggravation of symptoms, even when prescribed by a well-trained homeopath. Whether poorly-prescribed remedies could cause significant 'energetic' disturbances in a patient was contentious among interviewees. Most agreed, however, that harm could arise from failure to appropriately refer patients to a medical doctor, or inappropriate touching. **Conclusion:** Study findings interrogate the degree to which the risks of significant physical harm, omission or criminal activity each represent a necessary or sufficient precondition for health professional regulation. How regulators may contend with epistemic claims regarding potential minor adverse events that are difficult to evaluate within biomedical conceptual frameworks represents another significant challenge. Policy guidelines are needed to guide cogent regulation of traditional/complementary medicine practices, widely considered 'safer' than biomedical interventions, and commonly rooted in non-biomedical frameworks.

Unmet care needs, access to a regular medical doctor, and CAM use in Canadian adults with chronic pain: Findings from the National Population Health Study

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Background: Chronic pain is estimated to affect 1 in 5 Canadian adults, resulting in significant disability, a negative impact on health and quality of life, and a large financial and operational burden on the healthcare system. It is a complex and multifactorial phenomenon that remains to be poorly understood and has been recognized as one of the most pervasive and challenging conditions to manage by the medical community. Subsequently, the treatment of chronic pain is considered an effectiveness gap or a clinical area where current conventional treatments are not fully effective. As a result, more chronic pain sufferers are turning to complementary and alternative medicine (CAM) to manage their pain, the use of which has increased significantly over the past few decades. Literature suggests unmet healthcare needs can motivate CAM use, and this is directly related to the concept of access to a regular medical doctor. To the researcher's knowledge, this has not yet been studied within the context of Canadians with chronic pain at the population level.

Objectives: To explore the relationship between access to a regular medical doctor, unmet care needs and CAM use in adults with chronic pain.

Methods: A secondary analysis of data from Cycle 9 of the National Population Health Survey using binary logistic regression (n=1595).

Results: After controlling for demographics and health status indicators, the presence of unmet care needs predicted CAM use (p<0.001). Access to a regular medical doctor was not statistically significant in the model. Other statistically significant predictors of CAM use in adults with chronic pain were sex, education, income, employment, and restriction of activities.

Conclusion: Understanding health service access and unmet care needs are critical to developing service improvement strategies. This study indicates that people may be engaging in CAM due to shortcomings of the conventional health care system. This has implications for policymakers and healthcare professions to develop strategies to improve chronic pain management. These findings also support the necessity of more research into establishing safe and effective CAM practices via regulatory standards and a sound evidence base to support these therapies.

Pilot study of acupuncture to treat anxiety in children and adolescents

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Background: This pilot study investigated the use of acupuncture in the treatment of paediatric anxiety, using a waitlist control trial design.

Methods: Children with anxiety, age 8 to 16, were randomized to either the acupuncture or waitlist control group. Anxiety was measured using the Hamilton Anxiety Rating Scale for Children and Adolescents with Generalized Anxiety Disorder, Multidimensional Anxiety Scale for Children 2nd Edition (MASC-2) self-rated and parent-rated forms. **Results:** Twenty participants were enrolled in the study and 19 completed all the questionnaires to be included in the analysis. No difference in sociodemographic characteristics at baseline between the two groups. At the second assessment, the mean MASC-parent score for the Acupuncture group was significantly lower than the Waitlist group (65.6 (SD 15.0) compared to 81.0 (SD 11.9), p = 0.025) with an effect size = 1.13. The pre- and post-treatment comparisons were also significantly lower for both groups in the anxiety measures. In the Acupuncture group: MASC-Parent (p = 0.008, effect size 0.75), and the HAM-A (p < 0.001, effect size 1.4). In the Waitlist group: MASC-self (p = 0.002; effect size 0.4), MASC-parent (p = 0.048; effect size 0.75) and HAM-A (p = 0.007; effect size 1.21).

Conclusions: This study provided promising results on the potential use of acupuncture to treat children and adolescents with general anxiety. Future research, such as a randomized controlled trial with sufficient sample size to control for confounds and sham (placebo) comparator is warranted.

Preliminary results of a mixed methods study of effects of neurofeedback on cognitive impairment and fatigue in post-treatment breast cancer survivors

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Background: Cancer-related fatigue and postcancer cognitive impairment (PCCI) or "chemobrain" are distressing symptoms that may linger post-treatment. EEG biofeedback or neurofeedback brain training is a non-invasive, drug-free complementary and alternative medicine (CAM) therapy reported to help with a variety of conditions including fatigue and cognitive decline.

Objectives: This study aims to determine feasibility of a randomized controlled trial investigating the effect of neurofeedback on PCCI and fatigue in post-treatment cancer survivors.

Methods: Sixteen post-treatment breast cancer survivors were recruited for this pilot wait-list controlled study. Participants served as their own wait-list controls and received 20 NeurOptimalTM neurofeedback sessions over a ten-week period. Primary study outcomes were cognitive impairment as measured by an objective neurocognitive assessment, CNS Vital Signs, and a standardized patient-reported outcome (PRO) measure, the FACT-Cognition Scale. Secondary outcomes include fatigue as measured by the FACIT-Fatigue. Participants completed a follow-up interview five to ten weeks post neurofeedback therapy.

Results: Sixteen women were recruited and enrolled in the study, and to date 11 have completed the study protocol and follow-up including a semi-structured interview. Mean scores for the Total FACT-CoG increased significantly [F(1.595, 9.570) = 11.811, p = 0.004] over the treatment period as compared to the wait-list period, with a large effect size (partial eta squared = 0.663). Mean scores for the FACIT-Fatigue increased significantly [F(1.554, 9.323) = 17.484, p = 0.001] with a large effect size (partial eta squared = 0.745). Results of the CNS Neurocognition Index increased nonsignificantly [F(1.743, 10.457) = 1.731, p=0.224; partial eta squared = 0.224].

Conclusion: Statistically significant improvements in perceived cognition and fatigue levels, as well as promising trends on objective measures of neurocognition support the need for trials of neurofeedback in cancer survivors to manage debilitating symptoms. The identified challenges to participant recruitment will inform development of an RCT protocol.

Quality of randomized control trials and pilot trials in osteopathy according to the CONSORT checklist

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Background: Lack of scientific evidence is a reason frequently evoked for minimizing the potential contribution of complementary approaches. Even though the number of empirical publications in osteopathy have increased exponentially since 1980, little information is available on their quality of report.

Objectives: This study assessed quality of randomized control trials (RCT) and pilot trials identified through a systematic review of osteopathy-related trial publications.

Methods: Combinations of relevant keywords were searched for in CINAHL and Medline databases from 1980 to 2017. Published RCT or pilot trials describing an osteopathic intervention were included. Quality was assessed using the CONSORT checklist (CONsolidated Standards Of Reporting Trials) or its extension for pilot trials.

Results: One hundred thirteen RCT and 46 pilot trials were examined; 55% concerned musculoskeletal, 25% cranial, 14% visceral, and 6% combined treatments. On average, studies reported on 16 (IQR 9-28) items on the checklist. Less than half of the studies mentioned randomized trial (48%) or pilot (26%) in their title. Specific objectives were described appropriately for all RCT but only 54% of pilot trials. The method section was generally of good quality, except for the type of trial design description (25%), sample size calculation (40%), type of and implementation of the random allocation sequence (35%), and participant enrolment procedures (15%). Forty-five percent of the studies mentioned presence/absence of harms. The majority of the studies discussed their limitations (81%), but only 1/3 discussed the generalizability of the findings.

Conclusions: The quality of osteopathy-related RCT and pilot trial publications is similar to what was found for conventional medicine and other complementary medicine therapy studies. Objectives and discussion of pilot trials should reflect further the exploratory nature of such study design. Efforts are still required to increase the quality of report for the description of the randomisation technique, harms or unintended effects (or absence of), and the generalizability of the findings.

Evaluating stakeholder perceptions and health policy surrounding natural health product and medical cannabis regulation: A case study of Health Canada – A doctorate research proposal

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Background: Traditional, complementary and integrative medicines (TCIMs) are a staple for the delivery of or a complement to healthcare worldwide. TCIMs, inclusive of natural health products (NHPs) and medicinal cannabis (MC), are found in almost every country, yet their importance is often underestimated, despite their increased demand. Many countries now recognize the need to facilitate approaches that allow governments, healthcare practitioners and patients access to TCIMs in a safe, respectful, cost-efficient and effective manner, with Canada being no exception.

Objectives: To understand how these various stakeholders perceive they will be impacted by HC's choice to re-regulate NHPs and MC through three studies. **Methods:** The first study will be a scoping review which aims to evaluate NHP and MC regulation in Canada strictly by researchers in an academic setting. The second study seeks to elucidate from stakeholders why they believe what they do with respect to HC's proposed re-regulation of NHPs and re-regulation of MC. The third study involves conducting a policy evaluation of HC's reports about the regulations of NHPs and MC. **Results:** The first study will help to inform what research methods have been used in this area of research, and provide others with a valuable dataset which highlights the quality and quantity of articles published on this topic. The second study will identify the underlying reasons why select stakeholders hold their beliefs, with the objective of helping regulators and medical and allied healthcare practitioners to navigate the unique challenge of regulating NHPs. The third study will identify what interactions take place between stakeholders with a vested interest in one or both of these.

Conclusion: It is hoped that the proposed research will serve as a case study of HC's regulatory model, which can aid the development of regulatory strategies in other jurisdictions around the world.

Case study: Can craniosacral osteopathic manual treatment (OMT) decrease intensity and frequency of headaches in an adult with a past traumatic head injury associated with abducens nerve paralysis in childhood?

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Background: Headaches have a wide variety of types and causes, including traumatic head injury. If untreated, headaches can lead to important functional impairment on a daily basis. Several approaches are proposed to address this symptom. **Objectives:** This case study aims to describe the effects of craniosacral osteopathic treatment on a certain type of headaches, specifically related to a childhood head trauma that led to unilateral strabismus due to abducens nerve paralysis.

Methods: A 25-year-old man presented with frequent headaches following a head trauma 19 years ago. The headaches were suboccipital and left hemicranial with retro-orbital traction sensation. He underwent 2 surgeries, at 8 and 14 years old, for his strabismus. A validated headache scale (HIT-6) was used to evaluate functional impacts of the headaches pre and post intervention. The score of the HIT-6 range from 36 (activities never limited by the headaches) to 78 (always affected). The craniosacral osteopathic assessment was done independently by two evaluators and only the dysfunctions found by both were considered in treatments. Three treatments were done over a three-month period. The first two treatments addressed only craniosacral dysfunctions. Thoracic techniques were included in the last treatment to optimize the previous cranial treatments. **Results:** Initial cranial dysfunctions were resolved after treatments. The subjective feedback revealed an improvement in the headaches intensity and frequency. After each treatment, there was an absence of headaches for few days. The duration of headaches went from few consecutive days to an hour period. The general improvement of symptoms was confirmed by HIT-6 score that decrease from 60/78 to respectively 51/78 and 53/78. Persistent symptoms were associated by the patient to stress at work. **Conclusion:** Craniosacral OMT approach seems to have had positive impacts on intensity and frequency of headaches following a traumatic head injury during childhood for this patient. According to observations for this case, further research on the subject might highlight alternative treatment options for posttraumatic headaches such as craniosacral osteopathy. Further research should include global osteopathic approach as we noticed an improvement of the symptoms following the addition of thoracic techniques to craniosacral treatment.

Preliminary results from the Integrative Pediatric Oncology Program (IPOP) survey of OncANP members to determine clinical trends in naturopathic pediatric cancer care

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Background: The majority (61.0%) of pediatric oncology patients report use of complementary and alternative medicine (primarily self-directed). The high prevalence of use demonstrates the need for information regarding safety and efficacy of integrative pediatric cancer care. In order to assess trends in naturopathic/integrative pediatric cancer care, a survey was disseminated among OncANP members.

Objectives: Retrieved data from the survey will be used to guide the creation of a hospital based pediatric oncology program.

Methods: This survey was developed using the SurveyMonkey® platform and consisted of two main parts. Part 1 began with questions pertaining to the respondent's education, clinical practice and whether or not they treated pediatric cancer cases. Part 2 collected information regarding integrative therapies that respondents would recommend for pediatric cancer patients. Participants navigated through four main domains of treatment in Part 2, which included natural health products (NHPs), nutrition counselling, physical interventions and mental-emotional. The survey was disseminated among OncANP members and responses were collected for data analysis. Information such as intervention recommendations, dosing, contraindications and clinical pearls were analysed. **Results:** Approximately half of naturopathic doctors (NDs) surveyed do not treat pediatric cancer cases. The top 3 NHPs recommended were omega-3 (fish derived), vitamin D and probiotics. The top 3 mental/emotional recommendations were meditation. art therapy and mindfulness-based stress reduction. The top 3 nutritional recommendations were anti-inflammatory focused diet, dairy restricted diet and Mediterranean diet. The top 3 physical medicine recommendations were exercise. acupuncture and acupressure.

Conclusion: The primary reason that NDs are not seeing pediatric cancer cases is lack of public interest. There appears to be an even split between naturopaths who do and do not treat pediatric cancer. The results highlight naturopathic interventions with a high level of practical usage in childhood cancers which may be considered for inclusion in an integrative pediatric oncology program.

The combination efficacy and safety of body acupuncture and auricular acupressure for body weight control: A single-randomized shamcontrolled trial

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Background: Overweight and obesity have become a worldwide health issue because of modern lifestyle. Acupuncture is a characteristic external intervention and has been generally applied in body weight management. However, there are limited evidences among Hong Kong Chinese population.

Objectives: This study aimed to evaluate the efficacy and safety of the combination of body acupuncture and auricular acupuncture on weight control.

Methods: This was a single-blinded, randomized, sham-controlled study. In total, 72 participants aged between 18 and 65 years old with body mass index (BMI) \ge 25 kg/m2 were enrolled and allocated to either acupuncture group or sham acupuncture group equally. For the acupuncture group, disposable acupuncture needles were inserted into eight body points including Tianshu (ST-25), Daheng (SP-15), Daimai (GB-26), Qihai (CV-6), Zhongwan (CV-12), Zusanli (ST-36), Fenlong (ST-40), and Sanyinjiao (SP-6) with electrical stimulation. In addition, the acupuncture group received alternate unilateral auricular acupressure on four auricular points including Hunger, Shen men, Spleen and Stomach in each session. For the sham acupuncture group, Streitberger's noninvasive acupuncture needles were utilized at the same acupoints with identical stimulation modality. Besides, the identical embedded tapes were used on four nonacupoints at the helix as sham auricular acupressure control. The treatment duration was 8 weeks with 2 sessions per week and the follow-up period was 8 weeks. The primary outcome was the difference in body weight before and after treatment. The secondary outcomes included changes in BMI, waist circumference, hip circumference and body fat percentage from baseline to treatment endpoint and follow-up period.

Results: Compared to sham control, the combination of body acupuncture and auricular acupuncture could significantly reduce the body weight (from 83.83kg (SD: 16.87) to 82.36kg (SD: 17.13) versus from 78.64kg (SD: 16.70) to 78.10kg (SD: 16.50), p=0.015) and the BMI (from 31.51kg/m2 (SD: 5.26) to 30.95kg/m2 (SD: 5.35) versus from 30.29kg/m2 (SD: 4.49) to 30.10kg/m2 (SD: 4.56), p=0.016), but had no significant effect on waist circumference, body fat percentage and hip circumference during treatment and follow-up.

Conclusion: This study demonstrated the efficacy and safety of combination of body acupuncture and auricular acupuncture on body weight and BMI.

POSTER PRESENTATIONS

The importance of lymphatic osteopathic manipulative treatment (OMT) in the practice and training of osteopaths in Québec: A qualitative research study

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Background: The professionalization of osteopathy is imminent in Québec and it is therefore important to define the major branches of osteopathy and to outline new fields of research. The lymphatic system is one of these important areas, but it has been little explored in practice, training, and research.

Objectives: Explore the osteopathic conception of the lymphatic system in practice and in training, from the perspective of osteopaths practicing and teaching in Québec. **Methods:** Three teachers and four osteopaths were recruited using a convenience sampling. Data was collected through socio-demographic questionnaires; text books; pedagogical materials; school curriculum descriptions; audio-recorded interviews transcriptions; and a validation group interview using a constructivist design. Thematic analysis was used for individual interviews until saturation, and analysed data was submitted to all participants allowing for co-construction.

Results: The participants described the lymphatic system using the osteopathic principles of globalism, autoregulation, structure and function interrelations, and the importance of free fluid circulation. They defined the system as omnipresent and inseparable from osteopathic philosophy. The majority of participants admitted they do not treat lymphatics in their practice. Paradoxically, they also stated that every osteopathic technique can have a lymphatic impact. Osteopathic training on lymphatics is variable among programs and, most of the time, is nonexistent. All participants stated that the lymphatic system is as important as every other body system in osteopathy but acknowledged that it is overlooked. The participants pointed out the distinction between lymphatic OMT and other manual therapies. The distinctive aspects are the adaptation of the treatment method to the client using a specific evaluation; multiple techniques addressing the lymphatics directly; the osteopath's palpation skill; and osteopathic philosophy.

Conclusion: There was consensus about the gap between the primary importance given to lymphatics in osteopathic philosophy and the little place designated to it in practice and training.

The use of telemedicine in complementary medicine consulting: A survey-in-process of homeopaths and naturopaths in Ontario, Canada

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Background: Telemedicine, defined as the use of online and telephone-based technologies in health service delivery, has been increasingly adopted and studied within biomedical care contexts. Research indicates that these technologies, which offer convenience to patients, may also increase access to care for underserved populations and improve the geographic reach of non-local specialists. That said, telemedicine also has the potential to detrimentally impact the patient-practitioner relationship by reducing direct clinical contact. To date, notably little research has investigated the dynamics associated with telemedicine usage in the context of traditional, complementary and alternative medicine (TCAM) service delivery, increasingly in demand in North America. **Objectives:** The study has three primary aims: a) to determine the prevalence of telemedicine usage among professionalized North American TCAM practitioners; b) to investigate the rationale for telemedicine usage among such health care providers; and c) to explore the degree to which geographic and socio-demographic factors may impact TCAM practitioners' telemedicine usage.

Methods: Using a comparative, census-based online survey approach, homeopaths (n=770) and naturopathic doctors (n=1785), who are regulated professionals in the province of Ontario, Canada, will be invited to answer a set of telemedicine-related questions geared to the articulated study aims. These questions will be embedded within a larger survey constructed in line with the Tailored Design Method, using both quantitative and qualitative questions.

Results: Telemedicine-related responses will be analyzed and contextualized for participant demographics and geographical features, using both statistical and thematic analytic approaches.

Conclusion: Study findings promise to provide insight as to: a) the perceived advantages and challenges associated with particular telemedicine approaches; b) how to establish policies and best practice guidelines surrounding telemedicine usage in CAM practice; c) what areas require further research in the field of telemedicine as it pertains to TCAM service delivery.

Natural health products in integrative cancer care: Which ones have the most promising evidence from 218 recent reviews of human controlled studies?

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Background: A broad scoping and collation of the diverse integrative oncology research across all natural health products (NHPs) and cancer types has not been conducted, particularly since it is not very feasible to undertake a standard overview of systematic reviews due to the volume. This exploratory project investigated which NHPs warrant further detailed and comprehensive knowledge synthesis in our future research agenda. **Objectives:** To map "signals" of potential efficacy and safety of NHPs in human studies from systematic reviews in integrative oncology.

Methods: MEDLINE was searched for recent English systematic and comprehensive reviews from 2010-2017. From the included reviews, those human controlled studies that had positive and significant results were extracted for signals. To obtain key evidence for both efficacy and safety, primary outcomes were determined a priori as the following hard endpoints of cancer treatment: survival/mortality, treatment response,

recurrence/remission, disease progression/metastasis and stable disease. Of note, adverse events and non-significant results were not summarized and study quality was not appraised. A bibliometric analysis was also undertaken using Arrowsmith's Anne O'Tate software for trends by publication year and numbers per NHP category along with top journals.

Results: From the 1949 records screened, 218 reviews of NHPs were included which reviewed over 1000 unique human controlled studies. For the primary outcomes, leading nutraceuticals were melatonin, vitamin K and thymus extract; leading single botanical & fungi preparations were *Coriolus versicolor* (PSK/PSP), *Viscum album* and *Panax ginseng*; and leading Chinese & Asian medicine combination formulations were Kangai, Aidi and Shenqi Fuzheng injections (all three contained *Astragalus sp.*). Fish oil (with/without arginine or glutamine), probiotics, vitamin E, ginger, *Brucea javanica* and cannabinoids were leading NHPs for our secondary outcomes.

Conclusion: This project identified signals of potential efficacy and safety of leading NHPs in integrative oncology. Further research synthesizing the totality of evidence is required.

The inter-rater reliability of the frontal, temporal, parietal bones, and the spheno-occipital synchrondrosis mobility test as assessed through manual therapy

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Background: Few studies have attempted to establish the inter-rater reliability of the manual mobility tests of the cranial bones. Those who have, have had limited success. **Objectives:** The aim of this study was to investigate the interrater reliability of manual mobility tests of the frontal, temporal and parietal bones, and the spheno-basilar synchrondrosis, as assessed in osteopathic manual therapy.

Methods: Twenty-one subjects were evaluated by three experienced osteopaths, all on the same day, using a standard examination protocol. Prior to data collection, the three examiners relied on their clinical experience to review their anatomy palpation protocols and established a consensus of specific mobility requirements to identify a structure as restricted or not restricted. In groups of three, participants were evaluated separately by each osteopath who were blinded by a curtain. After each examination, the evaluators rotated tables to assess all three participants. Each structure was rated as restricted or not restricted. Examiners were blind to the subject and to each other's findings. Inter-rater reliability coefficients including the average pairwise percent agreements and the Fleiss' Kappa coefficients were calculated. We applied Landis and Koch classification to describe the global level of inter-rater reliability.

Results: All structures showed substantial reliability (Fleiss' Kappa coefficient between 0.6-0.8), with the exception of the lateral strain pattern of the SBS which was moderate (0.481), and an excellent pairwise percent agreements between 80-94%.

Conclusion: The results demonstrate consistency when three experienced osteopaths evaluate cranial bone mobility restrictions. The results also highlight the importance of consensus among practitioners for consistent palpation which is critical for the examination and guiding the treatment intervention.

The effect of early osteopathic manual treatment (OMT) care, after vaginal delivery, on pelvic health recovery

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Background: Vaginal birth is known to affect the pelvic floor and pelvis of delivering women. At this time, post birth, women mainly receive medical care focusing on suturing the perineal tears and preventing hemorrhage. It is common for women to also experience perineal swelling, pain and pressure which impair their walking ability and can be a sign of pelvic organ prolapse.

In this case study, the woman was 2-week post vaginal birth with a 3rd degree perineal tear. She experienced pressure to the perineum limiting her walking.

Objectives: Assess the effect of osteopathic manual treatment (OMT) treatments on symptoms of perineal pressure and impaired walking.

Methods: The patient received 3 OMT treatments over a four week-period. Treatments included visceral techniques to the uterus and its connections to iliacs and sacrum; muscle energy for the iliacs and sacrum; home exercises for the pelvic floor and pelvis; education on the use of support belt when walking and what activities to avoid.

Progress was measured using patient's subjective report of pelvic pressure on a scale of 10, walking duration/distance tolerated prior to experiencing pressure.

Results: Pelvic pressure was initially 8-9/10. Following first session, it decreased to 4/10, and increased back to 7/10 after 24 hrs. On her third visit, it was 3-4/10. Walking improved from feeling pressure around her house to walking for 1 hour, on flat trails, with 1-2 sitting pauses.

Conclusion: The results encourage us to further investigate post-natal OMT care for the treatment of pelvic pressure and its impact on walking ability post-natal. OMT is non-invasive and may be a valuable treatment option to help women recover post birth, resume walking which impacts their ability to care for their babies.

Fundamental study of a visceral pericardial osteopathic protocol on heart physiology

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Background: Research into scientific aspects of viscera in the field of osteopathy is in its early stages. It is important to define physiological mechanisms underlying osteopathic manipulations, such as heart rate variability (HRV) that reflects autonomous nervous system activity and consequently physical and mental well-being.

Objectives: This study aims to examine the effects of an osteopathic protocol for visceral thoracic manipulations (i.e. 5 techniques aimed to release the tensions on the fibrous pericardium (phreno-, sterno and vertebro-pericardial ligaments)) on aspects of HRV. **Methods:** Sixty-four healthy subjects, between 25 and 35 years old, were randomly and evenly distributed into three groups: control (n=21), placebo (n=21) and experimental (n=22). The HRV measurements were carried out over four weeks in order to assess the effect of this osteopathic protocol over time and on several dependent variables. More specifically, the HRV-frequency-domain values were analyzed, such as the low frequency (LF) and high frequency (HF) and the LF/HF ratio.

Results: Repeated measures revealed significant (p < 0.05) differences over time for LF/HF in the experimental group (pre-post and initial and final measurement differences) in comparison placebo. Moreover, it was noticed that the experimental group could a posteriori be analyzed as a result of two sub-groups based on LF/HF initial measurements.

Conclusion: For the first time, an investigation to correlate heart physiology outcomes to repeated osteopathic manipulations directed to the fibrous pericardium, has been carried out, suggesting the possibility for self-regulation according to his/her own physiology. This fundamental study is a first step towards understanding the physiological mechanisms underlying self-regulation resulting from osteopathic techniques. Even if these results were obtained out of a clinical framework, they could be useful for daily osteopathic practice. Future research will be directed to examining the benefits of such approach with patients presenting heart pathological symptoms or sternotomy thoracic surgery.

Theoretical foundations and efficacy of osteopathy: A philosophical approach

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Background: In recent years, osteopathy seems to be gaining popularity among patients. Anecdotal and empirical evidence is growing about the efficacy of this type of manual therapy. However, how the therapy works for different health conditions remains unclear, both in terms of mechanisms of action and contextual care factors surrounding successful treatment.

Objectives: To explore the theoretical foundations of osteopathy and its conception of efficacy, provide initial clues into the epistemological status of osteopathy and to assess the legitimacy of this discipline within the evidence-based medicine system.

Methods: We first conducted an exploratory focus group interview with the leaders and champions of a future Canadian Master's program of osteopathy to highlight issues concerning academic knowledge building. We also critically reviewed various scientific and philosophical literature to identify the scientific bases of osteopathy (e.g., concepts of holism and vitality), how efficacy is assessed in this research field, and how osteopathic interventions might operate beyond biomechanical theories.

Results: The results of our focus group and critical literature review suggested that the concept of specific efficacy is not sufficient to explain how osteopathic interventions work, which opened up to alternative explanations: e.g. contextual placebo effect (practitioner's effect, care ritual, etc.), natural course of illness/physical condition, and regression to the mean. The suggestion of both the expected effects and mechanism of action of the treatment by the practitioner was also discussed as an alternative explanation to the efficacy of osteopathy.

Conclusion: These findings suggest the existence of two opposing dissonant visions of efficacy: one specific of the treatment and one contextual. The latter has to be considered in practice. Next step is to explore ethical issues related to treating while taking account of contextual effects in an evidence-based medicine system, as some complementary and alternative medicine practitioners seem to do.

Beyond affluent wellness: Social justice-geared TCAIM service models in North America

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Background: The field of traditional, complementary, alternative and integrative medicine (TCAIM) has come under criticism in the North American context for its disproportionate focus on individual wellness, with little consideration for health's social determinants. Furthermore, the out-of-pocket costs of many TCAIM therapies have been described as rendering such care inaccessible to members of marginalized socioeconomic groups. However, there is an emerging but poorly-documented North American trend towards equitable delivery of TCAIM care that attends to more systemic causes of ill health.

Objectives: To develop a typology of the range of North American TCAIM services and clinical delivery strategies that specifically address health's social determinants and/or financial accessibility.

Methods: We undertook a narrative review of a wide range of documents, selected based on their adherence to our study aims. These documents included scholarly as well as grey literature materials, including organizational reports, webpages, news media accounts, and print materials published by clinicians.

Results: Our analysis identified six primary TCAIM clinical service / delivery types geared to social justice aims. These were: 1) free clinics (including single and multi-therapy settings, as well as TCAIM-only and 'integrative' models); 2) multi-patient treatment settings (e.g., community acupuncture clinics); 3) clinics geared to particular demographic groups (e.g., immigrants or ethno/linguistic groups, low-income patients, people with cancer); 4) flexible payment models (e.g., sliding scales, barter); 5) educational offerings (e.g., wellness-related classes for the underserved); and 6) global aid organizations (e.g., Natural Doctors International). More than one service/delivery type was at times present in a single setting.

Conclusion: A wide range of TCAIM clinical service and delivery models have emerged in the North American context that attend to health's social determinants and financial accessibility. Additional research surrounding the particular strengths and challenges associated with each of these models is warranted.

Assessing the immediate behavioural responses of hospitalized preterm babies during osteopathic manipulative treatment (OMT): A case series

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Background: Osteopathic manipulative treatment (OMT) has been shown to be effective in reducing the length of preterm babies' hospital stays. No associated adverse events have been reported. However, babies' tolerance while receiving OMT remains unclear. **Objectives:** To examine preterm babies' tolerance to an OMT session through their immediate behavioural responses.

Methods: In a quality of care assessment context, three hospitalized babies deemed medically stable whose gestational age at birth was 24^{5/7}, 33^{4/7} and 34^{4/7} weeks received one OMT session including somatic dysfunctions evaluation and treatment using myofascial release and cranial field techniques. Videos starting three minutes before and ending eight minutes after sessions captured babies, continuous display of their heart rate, respiratory rate, oxygen saturation, and ambient noise decibels. Babies' behaviour was examined independently by three qualified developmental care assessors using validated qualitative observation scales. Cumulative duration of the observed stress behaviours by manipulation type was calculated using MaxQDA video coding.

Results: OMT sessions were well tolerated by the babies (n=3), which even showed improved relaxation (n=3), quiet awake state (n=1), fluidity of movements (n=2) or better sucking activity (n=1). The cumulative duration of stress behaviours was in each case (n=3) shorter (by 40%, 52% and 91%) during osteopathic manipulations when osteopath hands were in place than during transitions such as first tactile contact, changes in osteopath hands position or baby position. Most of the stress behaviours appeared linked to environmental factors such as initial positioning and noise.

Conclusion: To our knowledge, this is the first report showing preterm babies' good tolerance to osteopathic manipulations specifically based on their immediate behaviour. Stimulations related to transitions or environmental factors during OMT should be controlled using protective developmental care measures in order to possibly reach even better global OMT session tolerance and possibly potentiate its benefits, which should be verified in further studies.

Canadian/US Integrative Oncology Study (CUSIOS): Protocol and study status

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Background: The Canadian/US Integrative Oncology Study (CUSIOS) is a prospective, observational study of advanced stage cancer patients receiving Advanced Integrative Oncology (AIO) care by experienced naturopathic doctors.

Objectives: (1) Measure survival of advanced stage breast, colorectal, ovarian and pancreatic cancer patients receiving AIO treatments; (2) Describe AIO treatments recommended by naturopathic oncologists; (3) Pilot the collection of health-related quality of life (HR-QOL) data; (4) Evaluate the cost of AIO care; (5) Qualitatively describe the experience of AIO care.

Methods: CUSIOS is an uncontrolled, prospective observational study in 11 North American clinics. The sample size is 400 patients, which includes 80 patients each in HR-QOL and cost-analysis sub-studies. Eligibility criteria include adults with confirmed stage 4 breast or colorectal cancer, or stage 3 or 4 ovarian or pancreatic cancer receiving care from a participating AIO clinic, who consent. Data regarding conventional treatments, AIO treatments, diagnosis and survival are collected and will be compared to the medical literature, and Surveillance, Epidemiology and End Results (SEER) database. Data from validated questionnaires and qualitative interviews are collected to evaluate HR-QOL, cost utilization and patient experience.

Results: Study recruitment began in January 2015 with 6 sites. Enrollment as of June 2018 is 278, with an expansion to 11 sites. Enrollment for HR-QOL is complete, and screening for cost analysis began in May 2018. Expected completion including follow up is July 2022.

Conclusion: This is the first multi-centre, prospective observational study evaluating survival outcomes for patients receiving AIO care in North America. Findings from the study will inform the profession and public of the potential impact that AIO has on survival and quality of life. In addition, this research will provide a thorough description of the range of therapies recommended by experienced naturopathic oncologists, cost utilization by patients, and a longitudinal analysis of patient experience.