HRI London 2019—Cutting Edge Research in Homeopathy: Presentation Abstracts

June 14–16, 2019 London

Homeopathy 2020;109:A1-A28.

Oral Abstracts

A001. Homeopathy and Expert Consensus Recommendations – Unlikely Bedfellows? New Research in Homeopathy and Expert Consensus Recommendations in Oncological Supportive Care

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Context: Homeopathy is the integrative medicine most widely used by patients with cancer in France. However, there were as yet no supportive care guidelines for this therapy. The International Homeopathic Society of Supportive Care in Oncology (www.shisso-info.com) aimed to make recommendations in order to propose to all health professionals concerned with supportive care, a homeopathic prescription tool respecting the principles of similitude, individualisation and of the infinitesimal dose.

Method: We used the method of expert consensus proposed by the French High Health Authority (HAS). It is a consensus method for writing a small number of concise, unambiguous recommendations, answering the questions asked. This method is proposed when there is a paucity of scientific argument on the subject, which is the case here.

Seven steering groups studied respectively cancer disclosure, surgery, chemotherapy, targeted therapies, radiation therapy, hormone therapy and the post-cancer period. These recommendations were presented during the plenary session which brought together some fifty physicians, pharmacists, oncologists or surgeons specializing in homeopathic supportive care.

Results: Thirty recommendations were discussed, amended and unanimously adopted or not during the plenary session. Some side effects, such as fatigue for example, are common to every patient, because the effects of cancer medication are stronger than an individual's reaction. Certain situations, however, require an individualised homeopathic consultation.

Conclusion: These recommendations are part of a program to improve good practice in supportive care. They are indicative and do not replace in any way an individualised homeopathic consultation. They are very safe to use as there are no medicine interactions and no significant side effects of homeopathic medicine. This is the first time that such an approach has been implemented in homeopathy circles. The same methodology could be used for other pathologies. Two years' hindsight has shown that they are indeed comfortable bedfellows

Keywords: Expert consensus, oncological supportive care, homeopathy

A002. Homeopathy and Environmental Challenges

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Homeopathy is growing in areas beyond human medicine because of its capacity to act on all living systems. In agriculture and cattle farms, especially those oriented to organic production, homeopathy has been a very useful tool and works in harmony with the concept of sustainability, including its application in biodynamic agriculture and agro-forestry.

In Brazil, more than 15 companies are established to manufacture homeopathic products for animal and vegetal use. The use of homeopathy has been present in zoos and protective organizations for wild animals, mainly in epidemic situations. This new perspective points towards a putative ecological role of homeopathy.

In a recent study, we verified the protective role of isotherapy in *Artemia salina* exposed to pesticides and heavy metals, highlighting that this crustacean is a known experimental model of eco-toxicology. The treatment of *Artemia* cysts exposed to glyphosate and lead with the respective isotherapeutic, induced better adaptation of these animals to the harmful medium, reducing the level of egg hatching and the incidence of malformations in the newborn nauplii.

Other parameters, like motility and general activity, also improved after the treatment. Physicochemical analyses of the water are still in progress, to provide some understanding about the mechanisms involved in this protection. In another set of experiments performed in vitro, the correspondence between changes in the dipole moment of homeopathic medicines and of the culture medium of responsive single cells could also be observed, using solvatochromic dyes. This suggests that electric resonance could be

a possible mechanism involved in the homeopathic treatment of an aqueous medium.

Under this hypothesis, another field study was set up, using the same method. The treatment of a natural water source with Phos 30 cH produced significant changes of the dipole moment in water samples harvested from different and distant locales of the same environment. That was similar to those effects observed in the medicine itself. The samples were taken before, and at different times after, water treatment. The same signals could be measured, even in distant points of the water flow, up to 72 hours after the immersion of *Phos* 30 cH into the source.

These studies show the importance of knowing how far the homeopathic signal can reach in nature, mainly in water, and unveils the putative role of homeopathy in recovering environmental disturbances.

Keywords: Environmental sciences, basic research, physicochemical models, high dilutions technology

A003. In-vitro Evaluation of the Anti-pathogenic Activity of Okoubaka aubrevillei Mother Tincture/3x in the Human **Gastrointestinal Tract Using the SHIME Technology** Platform

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Background/Aim: Okoubaka aubrevillei (Okou.) is known in homeopathy for its action on the gastrointestinal tract, e.g. in gastroenteritis and traveler's diarrhea. Within a Simulator of the Human Intestinal Microbial Ecosystem (SHIME® the modulating effect of Okou. on the activity of physiological human proximal colon microbiota and its preventive effect against gastrointestinal infections was evaluated.

Methods: Upon inoculation with fecal microbiota from a healthy donor, 4 parallel proximal colon compartments of the SHIME® were treated either with Okou. mother tincture or 3x in therapeutic doses, blank and ethanol control for one week. Using the "Okoubaka-adapted" microbial community from SHIME®, 48 hours "challenge tests" were performed with Enterotoxigenic Escherichia coli (ETEC) and Salmonella enteritidis in 4 different doses between 10³–10⁸ CFU for ETEC and $10^3 – 10^6$ for Salmonella, considering the minimum infectious doses. Concentrations of the pathogens and short-chain fatty acids (SCFA) production were measured at 0, 24 and 48 h. The experiments were done in triplicate and normalized to ethanol control.

Results: Both Okou. mother tincture and 3x were capable of restricting the colonization of Salmonella enteritidis and ETEC at 3 of the 4 pathogen doses. A stronger antipathogenic effect was observed for the mother tincture, which included a reduction of 1.1 log-units of Salmonella (p < 0.001) and 2.0 units of ETEC (p < 0.001) after 24 h of incubation for the lowest pathogen dose.

Total SCFA levels remained unaffected, but propionate and butyrate slightly increased during the first 24 h and remained high during the 24–48 h time interval, accompanied by a decreased acetate production which indicates a "cross feeding" process from acetate to health-related butyrate.

Conclusion: An activating effect of the intestinal microbiome's resistance can be postulated for both Okou. mother tincture and 3x.

Keywords: Okoubaka, microbiome, SHIME[®], in vitro

A004. Immobilisation of Solvatochromic Dyes on Transparent Membranes; a Simple and Effective Method for **Investigating the Physics of Homeopathic Potencies** Steven J. Cartwright¹

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Background and Aims: Solvatochromic dyes have demonstrated themselves to be effective detectors of homeopathic potencies. Current research is directed at the immobilisation of solvatochromic dyes onto transparent membranes in order to examine in detail the primary interaction between a range of different homeopathic medicines across potency scales.

Methods: It has been found that a number of solvatochromic dyes can be covalently immobilised onto cellulose membranes, thereby allowing a direct examination of the primary interaction between homeopathic potencies and molecular detectors. Immobilisation means that dye aggregation cannot occur and therefore a much clearer picture is beginning to emerge with respect to the kinetics and thermodynamics of potency-dye interactions.

Results: One surprising finding already emerging is that the interaction between dyes and potencies is hysteretic or S-shaped. This behaviour is characteristic of positive feedback loops or auto-catalytic processes where a process selfstrengthens over time before eventually reaching a maximum. Results suggest some kind of resonant interaction between potencies and dyes is taking place, the strength and development of which is dependent upon starting conditions and the electronic and structural features of the dye used. Further findings indicate that potencies are not constant in their strength but fluctuate over time.

Conclusions: What the possible causes of both the hysteretic behaviour of potencies and the fluctuations in potency strength over time are, and what they mean for homeopathy in general, will be discussed, along with what these results may be telling us about the likely identity of potencies.

Keywords: Solvatochromism, immobilisation, feedback, hysteresis, resonance

A005. A Homeopathic Medication Can Improve Upper **Respiratory Tract Infections in COPD Patients: EPOXILO Cohorts Study**

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Background: Exacerbations of Chronic Obstructive Pulmonary Disease (COPD) can be triggered by Upper Respiratory Tract Infections (URTIs), viral aetiology being of increasingly higher importance. A homeopathic approach to viral URTI in COPD patients could help reduce its frequency and related exacerbations.

Methods: Prospective, cohorts, multi-center study in Cantabria (Spain), with 219 COPD patients taking a weekly dose of the homeopathic medicine Oscillococcinum (HG = 109) or not (CG = 110) added to conventional treatment and following usual practice. Main objective was measuring the number of URTIs (follow-up of 4-5 months). Secondary endpoints included duration of URTIs, number and duration of COPD exacerbations, use of drugs, quality of life and adverse events.

Results: There was a significant reduction in the mean number of URTIs in HG compared to CG (0.51 vs 1.04), with a difference of -0.52 (CI 95% [-0.84; -0.20], p = 0.001) and 3.3 times more likelihood of suffering ≥2 URTI episodes in CG (p = 0.003). The mean duration of the episodes was reduced in HG patients (3.57 vs 5.22 days; p = 0.012). When looking at the exacerbator phenotype patients, there was a significant decrease in number of URTIs (0.54 vs 1.31; p = 0.011) and fewer COPD exacerbations (0.9 vs 1.5; p = 0.037). The prescription of exacerbation-corticoids was decreased in both groups between baseline and visit 2, but more reduced in HG (22.1% vs 7.5%; p = 0.005). Other variables did not reach statistically significant differences between groups.

Conclusions: The use of this homeopathic medicine by COPD patients may have a beneficial impact in reducing the number and duration of URTIs and can positively impact the number of COPD exacerbations in patients with the exacerbator phenotype. Confirmation with studies with a greater sample size and a longer follow-up should be pursued.

Keywords: COPD, homeopathy, URTI, exacerbation, cohorts

A006. Replication and Meta-Analysis of Specific Effects of Homeopathically Prepared Tin (Stannum metallicum 30x) with a Cress Seedling, CuCl₂ Crystallisation 'Fingerprint', **Approach**

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Background and Aims: Basic homeopathic research requires stable and reliable test systems to detect biological effects of homeopathic preparations. Baumgartner et al. (2012) described a test system, which revealed specific effects of a potentized *Stannum met*. 30x preparation (nominal dilution of 10^{-30} of the original substance) compared to water 30x as control in a bio-assay using cress (Lepidium sativum L.). The bio-assay is based on cress seed germination, CuCl₂x2H₂O crystallization of the cress extracts, and subsequent computerized image analysis of the crystallization

In the present study we performed a replication trial at two independent laboratories, employing meticulous methodology, among which the integration of Systematic Negative Control (SNC) experiments.

Results: Analysis of the data of the replication trial revealed the same data structure in both projects regarding directionality and relative effect size of the homeopathic treatment. SNC experiments did not yield evidence for experimental instabilities, indicative of a robust test system. A meta-analysis of the pooled data of both trials revealed a highly significant treatment effect of Stannum met. 30x, and no interaction with experimental day. In a subgroup analysis we identified that the spatial region of the crystallization patterns, where the potency treatment effect manifests, was predominantly confined to the geometrical centre of the crystallization plates - which is in agreement with the precursor study.

Conclusions: We were able to establish a test system yielding reproducible biological effects of an ultra-molecular homeopathic preparation when replicated in ten independent experiments in two laboratories. Meta-analysis of the data of both trials yielded a highly significant treatment effect. These ground-breaking results point to a promising potential of the method to contribute to basic homeopathic research and call for developing a theoretical model to understand the effects observed.

Keywords: Pattern formation, bio-assay, meta-analyreproduction trial, systematic negative control experiments

A007. Homeopathic Treatment Ameliorates Fatigue and **Attentional Deterioration in Radiotherapy Breast Cancer Patients**

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Patients with breast cancer experience psychosocial distress such as anxiety, depression, fatigue, and cognitive disturbances. Both fatigue and cognitive dysfunction have been observed as post-treatment outcomes of chemotherapy and/or radiotherapy.

The PPI test represents an operational measure of information-protective pre-attentional mechanisms. PPI is a neurological phenomenon in which a weaker acoustic prepulse (delivered via headphones) inhibits the reaction to a subsequent strong startling pulse. The reduction of the response amplitude (measured by electromyographic activity from the orbicularis oculi muscle) reflects the ability of the nervous system to temporarily adapt to a strong sensory stimulus when a preceding weaker signal is given. PPI is an objective tool for fatigue evaluation.

In a randomized, double blind, IBR-approved study, 57 female patients who underwent chemotherapy and adjuvant whole breast radiation in the radiation department at Sheba Medical Centre, and who gave written consent for participation, were included in the study: 38 received homeopathic treatment and 19 received placebo.

All patients were evaluated at the beginning, during, end and one month after completing radiotherapy for: (i) fatigue level, utilizing the Fatigue Symptom Inventory (FSI); (ii) attention performance, utilizing the Pre-Pulse Inhibition (PPI) task; and (iii) anxiety level, utilizing both the startle response test and examining the Galvanic Skin Response (GSR) differences.

At baseline, both treated and placebo groups showed similar impaired level of auditory-sustained attention (ASAT; measured by pre-pulse inhibition), probably as a consequence of recent chemotherapy.

One-month after radiotherapy completion, while the placebo ASAT performance further deteriorated, a significant improvement (to normal performance) was observed in the homeopathic treatment group.

Keywords: Homeopathy, breast cancer, fatigue, radiotherapy

A008. Outcome-Specific Review of Controlled Clinical Studies with Homeopathic Medicines

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Background: Though there exists a considerable number of systematic reviews of clinical homeopathy studies, they are limited regarding literature sources and study type. Furthermore, a comprehensive update is needed.

Aim: The aim was to conduct an extensive systematic review focusing on the investigated indications and outcomes of the original studies in order to provide a clear view of the existing evidence for each particular indication, to reveal academic voids and to enhance the applicability of the results for therapeutic practice.

Method: In addition to available studies from previous reviews, an extended literature search was conducted considering also 'grey' literature (e.g. theses, conference proceedings). Six medical databases (Medline, Embase, Cochrane Central Register of Controlled Trials, SCOPUS, Science Citation Index Expanded and LILACS), four databases for complementary medicine (CORE-Hom and CAM-Quest®, AMED and CINAHL), as well as 25 databases for theses and dissertations, were searched and complemented by manual references. Search limits were set from 01.01.1980 to 30.06.2017. The study records were managed by means of the citation manager Endnote® and were transferred into a previously piloted and standardized data-handling template (Excel®). Publication type, study aims and target population, study design, sample size and outcomes, as well as intervention details such as potencies, dosage, type of homeopathy and comparator, were extracted from the included reports.

Results: 600 original studies in 202 medical conditions could be included in the review. For 52 conditions, at least two controlled studies for the same homeopathic intervention could be identified. They will be presented, using tables for the different clinical indications, and discussed regarding the study details (e.g. design, sample size, homeopathic method).

Keywords: Review, research methodology, clinical practice

A009. How Homeopathy is Treated in Meta-analyses Robert Hahn¹

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Many scientists reject homeopathy because there is no plausible mechanism of action. However, medical care today is evidence-based, where a mechanism is not crucial. With abundant literature, evidence is obtained by meta-analyses and systematic reviews. Sadly, several meta-analyses authored by classical scientists and skeptics, where homeopathic treatment is compared to placebo (water), show evidence of manipulation and bad judgment.

The story starts in 1997 when Klaus Linde and coworkers identified 89 clinical trials that showed an overall odds ratio of 2.45 in favor of homeopathy over placebo. This difference was statistically significant. Linde reported a trend toward smaller benefit from studies of the highest quality, but the 10 trials with the highest quality (highest Jadad score) still showed homeopathy had a statistically significant effect.

These results challenged academics to perform alternative analyses that, to demonstrate lack of effect, relied on extensive exclusion of studies, often to the degree that conclusions were based on only 5-10% of the material, or on virtual data. Such extensive exclusion exercises, created in retrospect, opens the way for the authors to manipulate the outcome by creating statistical Type II errors and flip-flop phenomena. The ultimate argument against homeopathy is the "funnel plot" published by Shang's group in 2005. However, the funnel plot model is flawed when applied to a mixture of diseases, because studies with expected strong treatment effects are, for ethical reasons, powered lower than studies with expected weak or unclear treatment effects.

To conclude that homeopathy lacks clinical effect, scientists must overlook more than 90% of the available

clinical trials. Alternatively, flawed statistical methods must be applied.

Keywords: Homeopathy, study quality, meta-analysis, randomized controlled trials

A010. Effects of Homeopathic Preparations of *Mercurius* corrosivus on the Growth Rate of Mercury-Stressed Duckweed *Lemna gibba* L. as a Function of Different Stress Levels

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Background and Aims: We developed a bioassay with mercury-stressed duckweed (Lemna gibba L.) to study potential effects of homeopathically potentised mercury(II) chloride (Mercurius corrosivus). Furthermore, the response of this bioassay to homeopathic treatments as a function of stress intensity was also of interest.

Methods: A bioassay with arsenic-stressed duckweed (Lemna gibba L.) was adapted for the use of mercury as stressor. Plants were poisoned with mercury(II) chloride at two different intensities (slight/severe) for 48 hours. Afterwards plants grew in either Mercurius corrosivus (24x to 30x) or water controls for seven days. Growth rates of the frond (leaf) area were determined using a computerised image analysis system. Six independent experiments with potentised Mercurius corrosivus were performed, three for each stress level. Additionally, six systematic negative control (SNC) experiments with water were conducted (three for each stress level) to investigate the stability of the experimental set-up. All experiments were randomised and blinded.

Results: Highly standardised conditions were achieved by using a specific growth chamber, leading to very small coefficients of variance ($\approx 2\%$). The SNC experiments did not yield any significant effects, providing evidence for the stability of the experimental system. Growth rates of slightly stressed duckweed were significantly enhanced after application of Mercurius corrosivus 24x–30x compared to the controls. Growth rates of severely stressed duckweed were significantly reduced compared to the controls.

Conclusion: The test system with Lemna gibba L. yielded evidence for specific effects of Mercurius corrosivus 24x–30x, namely a growth enhancement for duckweed that was slightly stressed and a growth reduction for duckweed that was severely stressed by mercury. The Lemna gibba L. bioassay is developing into a very useful tool for homeopathic basic research, since it revealed specific effects of potentized Arsenicum album after arsenic stress, and effects of potentized Mercurius corrosivus after mercury stress, and might be used in the future for investigation of the Simile principle.

Keywords: Mercury-stressed plant bioassay, stress intensity, Mercurius corrosivus, duckweed, Lemna gibba L.

A011. Homeopathic Preparations in the Low Potency Range Studied by Means of Pattern Formation in Evaporating Droplets: Influence of Succussion Stroke Number Maria Olga Kokornaczyk¹, Sandra Würtenberger², Stephan

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Background and Aims: Evaporation-induced pattern formation in droplets has been applied to characterize homeopathic preparations at high and low potency levels. Here we investigated whether the droplet evaporation method (DEM) may identify differences in succussed vs. unsuccussed homeopathic preparations, and in potencies prepared with different succussion stroke numbers in the low potency range.

Materials and Methods: In the present experimentation we analyzed five potencies (Echinacea 2x, Baptisia 3x, Baptisia 4x, Luffa 4x, and Spongia 6x) prepared in three variants each: potentized by the application of (i) 100 or (ii) 10 succussion strokes between the consecutive dilution steps, and (iii) prepared as an unsuccussed, only gently mixed, control. The experimental set-up stability was examined by positive control experiments. The DEM experimental protocol consisted of the evaporation of droplets of the analyzed potency per se, placed on microscope slides and under controlled conditions. The resulting patterns were photographed in dark field. The images (4026 in total) were subjected to computerized pattern evaluation, consisting of the measurement of their grey-level distribution, aspects of texture, and fractality.

Results: In all five analyzed homeopathic preparations, the succussed (100 and 10 times) and unsuccussed variants could be significantly differentiated by means of at least three of the five analyzed image evaluation parameters. Significant differences between all variants were found only for potency levels 4x and higher (Baptisia 4x, Luffa 4x, and Spongia 6x) in one parameter per preparation. In most cases, the application of succussion strokes reduced the size, homogeneity, and complexity of the DEM patterns. The control experiments showed reasonable experimental model stability.

Conclusions: Phenomenological study of homeopathic preparations in the low potency range, prepared with different succussion stroke numbers, may contribute to a better understanding of the changes that the material, which is still present at low potencies, undergoes during successive potentization steps.

Keywords: Evaporation, patterns, homeopathy, low potencies

A012. Further Data on Wheat Germination and Silver **Nitrate: Low and Medium Dilutions**

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Background: In pilot studies (GIRI 2016, HRI 2015), wheat grains were observed under aqueous low solutions of silver nitrate, either diluted in distilled water in steps of 1:10 by pipetting only ("e") or diluted and agitated ("x"). Untreated distilled water served as additional control (W0). Probes were applied blindly. Germination rates after 28h were higher under "x" than under "e" (p < 0.01 in both studies). System stability was tested and found adequate (GIRI 2018), silver nitrate concentrations were measured and found correctly prepared (GIRI 2019), and it was shown that agitated water did not lead to enhanced germination versus non-agitated water, thus excluding the possibility of an effect of higher oxygen saturation in x-probes (GIRI 2018).

Aim: Following up on the pilot studies, the aim was to investigate the influence of silver nitrate on wheat germination at low $(10^{-2} \text{ to } 10^{-10})$ and medium $(10^{-11} \text{ to } 10^{-24})$ dilutions.

Method: Experiments were performed in Austria $(10^{-2} \text{ to } 10^{-10})$ and Germany $(10^{-2} \text{ to } 10^{-24})$. Experimental conditions were as similar as possible to those in the pilot study, apart from the fact that silver nitrate 10^{-2} (not 10^{-1}) served as mother tincture.

Result: After 28h, germination rates (N grains = 2200) were 54.5±16.04% of W0 probes, 44.76±17.16% of e-probes (N = 9100) and $48.12\pm17.41\%$ of x-probes (N = 9100). Germination rates were thus higher under x than under e, surpassing the e-values by 7.5% for the overall pooled data $(10^{-2} \text{ to } 10^{-24}) \ (p < 0.01)$, and by +6.7% for 10^{-2} to 10^{-10} , +8.2% for 10^{-11} to 10^{-17} , and +13.7% for 10^{-18} to 10^{-24} .

Conclusion: The experiments suggest that agitation of molecular probes can have effects that would also deserve consideration in mainstream biology and medicine.

Keywords: Low dilution, silver nitrate, wheat

A013. Demographic Review of Outcomes in an NHS **Homeopathy Clinic**

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This qualitative research project has been developed from a data-set whose primary objective was to provide a detailed factual profile of a fully functional National Health Service (NHS) Homeopathy Clinic.

A six-year statistical review of all patients seen at the NHS Tayside Homeopathy Clinic has involved the collation of a) socio-economic and demographic data, b) pre-existing conventional drug data, and c) illness-category data, each measured against outcomes, established by: i) physicianmeasured significance scores in an unselected cohort of 600 patients, and ii) a subset of 120 patient-reported outcomes from actively reviewed cases in 2018.

The observed patterns of outcome are presented in the context of detailed health, social and socioeconomic profiling of attenders at this NHS Clinic.

Keywords: Qualitative, socio-economic, NHS, homeopathy, demographic

A014. In-vitro Testing Homeopathic Drugs on Bronchial Cells Marta Marzotto¹, Shahram Shahabi², Paolo Bellavite¹

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The aim of the research is to assess any protective invitro activity of homeopathic remedies, used in ailments characterized by cough symptoms, on bronchial epithelial cells (16HBE). We are studying the effects on healthy cells and cells intoxicated with cigarette smoke extract (CSE), where CSE intoxication should mimic the pathologic state of airway epithelium associated with cough.

The cells are seeded in 96-well microplates at a density of 2.5×10^4 cells/well in 2% FBS-EMEM medium. Liquid extract of cigarette smoke (CSE) is prepared by bubbling smoke into PBS solution, diluted at suitable concentration to obtain sub-maximal toxic effects. Normal and CSEtreated cells are treated for 24h or 48h with various doses of homeopathic drugs (Hyland's, Los Angeles, USA) traditionally indicated for people with upper respiratory tract infections, such as Drosera rotundifolia, Pulsatilla pratensis, Nux vomica, Allium cepa, Natrum muriaticum and Kalium bichromicum and others, or solvent ethanol/water as control. Parameters of cell viability (WST and Crystal Violet) and cytokine production (IL8, IL6, TNF- α , IP-10 and others) are measured.

Preliminary findings from dose-response studies indicate that most tested drugs have no effects on cell viability, indicating that they are safe. *Drosera* low dilutions (2x–5x) exert a small but significant protective effect in CSE-challenged cells. *Kalium b.* 5x and *Nux vomica* at 3x dilution significantly decrease cell viability in both normal and CSE-treated cells, while the same dose increases the release of IL8 and IL6. Interestingly, the chemokine IP-10, (interferon-induced chemoattractant for monocytes/macrophages and T cells) decreases when the cells are treated with *Kalium b.* and also with *Drosera* 5x, suggesting that this chemokine may be a sensitive and specific new target in bronchial cells.

In conclusion, this model provides an interesting tool for the investigation of the therapeutic properties of common homeopathic drugs on normal and CSE-stressed bronchial epithelial cells.

Keywords: Bronchial cells, in vitro, Drosera, Kalium bichromicum

A015. The High-Quality Randomised Controlled Trials of Homeopathic Treatment, as Defined by Systematic Review and Meta-Analysis

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Background: In our programme of systematic reviews, assessment of internal validity (IV) and model validity (MV) of randomised controlled trials (RCTs) of individualised and non-individualised homeopathic treatment (IHT and NIHT respectively) has enabled us to rate placebo-controlled RCTs as high, moderate or low study quality. Assessments of IV and external validity (degree of pragmatic or explanatory study attitude) have recently been achieved for other-than-placebo (OTP)-controlled RCTs of IHT and NIHT.

Aims: To examine the totality of clinical evidence in homeopathic treatment across the four RCT designs, with particular focus on high-quality studies and their meta-analysis.

Methods: The 90 RCTs that were included in our four prior meta-analyses comprised the data-set. A study was rated 'high quality' if it had high IV and acceptable MV (placebo-controlled trials) or if it had high IV and suitable pragmatic or explanatory attitude (OTP-controlled trials). One main outcome measure per RCT was identified and used in sensitivity analysis based on high study quality.

Results: The quality rating was 'high' for 5 RCTs, 'moderate' for 31, and 'low' for 54. Four of the high-quality trials were placebo-controlled (3 IHT, 1 NIHT): Jacobs et al (Pediatrics 1994; childhood diarrhoea); Jacobs et al (Pediatr Infect Dis J 2001; otitis media); Bell et al (Rheumatology 2004; fibromyalgia); Colau et al (Drugs RD 2012; menopausal syndrome). One was OTP-controlled (a pragmatic study of IHT): Peckham et al (Homeopathy 2014; irritable bowel syndrome, IBS). Analysis of the high-quality trials identified a treatment effect favouring homeopathy over placebo (odds ratio = 2.05; 95% confidence interval, 1.33 to 3.15; n = 4; p = 0.001); there was no significant difference between homeopathy and usual care for IBS.

Conclusions: There are 5 high-quality RCTs of homeopathic treatment, containing evidence of a distinct effect of homeopathic medicines compared with placebo. Additional high-quality RCT research in homeopathy is necessary to enable more complete and decisive data interpretation.

Keywords: Individualised, non-individualised, randomised controlled trials, systematic review, meta-analysis

A016. Control of Liver Enzymes in Magellanic Penguins (*Spheniscus magellanicus*) Through Ultra-diluted Medicine Franscinne Narita^{1,2}, Cidéli Coelho^{3,4}

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Magellanic penguins reproduce along the coast of Argentina, Chile and the Falkland Islands. Brazil is part of the migratory route of these animals, which are found in a debilitated state on the coast and sent to rehabilitation centers. When they are not able to be reinserted, they are sent to zoos and aquariums. At Sabina, Escola Parque do Conhecimento, the penguins receive check-ups every six months, including blood collection (hemogram and biochemistry).

Objective: To show the results of homeopathic treatment on the liver enzymes (ALT-TGP/AST-TGO) of Magellanic penguins kept in zoos. ALT enzymes are mainly found in the cytosol of hepatocytes and muscle cells, and act on the catabolism of amino acids and the transport of nitrogen between organs (baseline values: 16–140 U/L). AST exists in multiple tissues, mainly in the liver and muscles (baseline values: 90–300 U/L).

Methods: Ten Magellanic penguins presented liver enzyme changes at their annual check-up and were treated with four globules of *Carduus marianus* 6 cH, once a day, for 30 days, and were assessed again through new tests. The data was analyzed using the Mann-Whitney U-test, with p < 0.05 considered a statistically significant difference.

Results: In animals treated with Carduus, there was a mean decrease in ALT values, from 141.2 \pm 61.5 U/L to 65.3 \pm 28.7 U/L (p < 0.05), as well as a mean decrease in AST values, from 394.7 \pm 113.7 U/L to 223.2 \pm 116.7 (p < 0.05). The response to the homeopathic treatment was similar to the allopathic treatment in previous check-ups, but without any side effects and being easy to administer.

Conclusion: Homeopathic treatment for penguins living in zoos and aquariums is a good option, with excellent results and animal wellbeing.

Keywords: Homeopathy, Carduus marianus, high dilution

A017. Effect of Adjuvant Homeopathy with Usual Care in Management of Thrombocytopenia Due to Dengue – a Comparative Cohort Study

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Background: Dengue is an emerging threat to public health. At present no clear modalities are available for prevention and management of thrombocytopenia due to dengue. This presentation reports the clinical outcomes of integrative homeopathic care in a hospital setting during a severe outbreak of dengue in New Delhi, India, during the period October to December 2015.

Methods: Based on preference, 138 patients received a homeopathic medicine along with usual care (H+UC), and 145 patients received usual care (UC) alone. Assessment of thrombocytopenia (platelet count <100,000/mm³) was the main outcome measure. Kaplan-Meier analysis enabled comparison of the time taken to reach a platelet count of 100,000/mm³.

Results: There was a statistically significantly greater rise in platelet count on day 1 of follow-up in the H+UC group compared to UC alone [mean difference = 12,337; 95% confidence interval (CI) = 5,421 to 19,252; p = 0.001]. This trend persisted until day 5 [mean difference = 14,809; 95% CI = 1,615 to 28,004; p = 0.02]. The time taken to reach a platelet count of $100,000/\text{mm}^3$ was nearly two days earlier in the H+UC group compared to UC alone [H+UC: 3.44 days \pm standard error of the mean (SE) 0.18; 95% CI = 3.08 to 3.80; UC: 5.28 days \pm SE 0.29; 95% $\overrightarrow{CI} = 4.71$ to 5.86; p = 0.0001].

Conclusion: These results suggest a positive role of adjuvant homeopathy in thrombocytopenia due to dengue. Randomised controlled trials may be conducted to obtain more insight into the comparative effectiveness of this integrative approach.

Keywords: Dengue, thrombocytopenia, homeopathy

A018. Effectiveness of Homeopathic Medicines as Add-on to **Institutional Management Protocol for Acute Encephalitis** Syndrome in Children: an Open-Label Randomized Placebo-**Controlled Trial**

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Background: Acute encephalitis syndrome (AES) is endemic to certain parts of India, with limited treatment options. In our initial exploratory comparative observational study of 151 patients with AES, there was significantly reduced mortality with adjunctive homeopathy compared to institutional management protocol (IMP). The present randomized placebo-controlled trial brings more statistical rigor to this research program.

Methods: This study was conducted at a pediatric unit from 2013 to 2015. Children aged > 6 months and \leq 18 years and receiving IMP were randomized to receive adjunctive homeopathy (n = 325) or placebo as control (n = 323). The primary effectiveness analysis was based on Glasgow Outcome Scale (GOS). Morbidity was assessed using the Liverpool Outcome Score for Assessing Children at Follow-up. Analysis was by intention to treat.

Results: A total of 612 children were analyzed (Homeopathy [H] = 304; Control [C] = 308). The primary outcome, GOS, differed significantly between H and C groups. There was 14.8% death/neuro-vegetative state in the H group compared to 29.8% in the C group. Relative risk was 0.49 (95% confidence interval [CI]: 0.36 to 0.68), with absolute risk reduction of 15.0% (95% CI: 8.6 to 21.6%). Number needed to treat to prevent one additional death/neuro-vegetative state was 6.6 (95% CI: 4.6 to 11.6). Proportional-odds analysis also revealed a greater effect in the H group: odds ratio, 0.40 (95% CI: 0.27 to 0.60). The most frequently used medicines were Belladonna (n = 116), Stramonium (n = 33), Arsenicum album (n = 25), Sulfur (n = 18), Opium (n = 17), and Nux vomica (n = 10).

Conclusion: Adjunctive homeopathic medicines may improve clinical outcomes associated with AES. Further randomized and controlled studies, using double-blinded trial design, are recommended to discover if the current findings may be corroborated.

Keywords: Acute encephalitis syndrome, adjunctive homeopathy, India, Glasgow Outcome Scale

A019. Randomised Controlled Trials

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There have been over 180 randomised controlled trials of homeopathy published in the English language peer reviewed scientific journals since 1940. Do these trials prove that homeopathy works?

Clare describes her 15-year journey to answer this and other related questions:

What are randomised controlled trials? How are they designed, conducted and interpreted? What is the difference between a randomised controlled trial and an observational study? What are pragmatic trials? What do 'Homeopathy' trials test? Treatment by homeopaths? Homeopathic medicines, or something else? Can we design trials that will help patients, clinicians, and homeopaths make the best decisions?

This talk illuminates this modern 'scientific' tool, and the economic, political and cultural forces that continue to shape trials, and concludes by offering suggestions for homeopathy trials in the future.

Keywords: Randomised controlled trials, pragmatic

A020. Challenging Inaccurate Influential Literature on Homeopathy

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In recent years, the science and politics of homeopathy have become closely intertwined, with public access to homeopathic treatment and training, as well as regulatory issues, becoming increasingly determined by how the evidence base is interpreted by decision-makers.

It is therefore of great concern that over the same period, we have seen an ever-increasing divergence between the actual status of the homeopathy evidence base as understood by experts in the field, and how this data is reported by academics from other disciplines and in the mainstream media.

The most striking example of academic misreporting is the Overview Report published by the National Health and Medical Research Council (NHMRC) in 2015. This report, commonly known as 'The Australian Report', found 'no reliable evidence' that homeopathy is effective.

Despite being scientifically flawed and highly inaccurate, the Australian Report is currently the most influential clinical research publication on homeopathy, having generated damning headlines and been cited by decision-makers worldwide.

In 2017 this trend of misreporting continued with publication of the European Academies' Scientific Advisory Council's anti-homeopathy position statement, "Homeopathic products and practices: assessing the evidence and ensuring consistency in regulating medical claims in the EU".

Despite claiming to have based its conclusions on 'excellent science-based assessments already published by authoritative and impartial bodies', the 'EASAC Statement' quotes the infamously flawed Shang et al. meta-analysis published in 2005, a non-scientific and widely criticised document produced by a UK Parliament Select Committee in 2010, and the 2015 Australian Report.

In this session we will: review the key scientific flaws in the NHMRC Overview Report and EASAC Statement; look at the impact these publications have had on the homeopathy sector worldwide; and report on the status of strategies employed by the Homeopathy Research Institute, and our international collaborators, to challenge their inaccurate findings.

Keywords: Homeopathy, Australian Report, NHMRC, EASAC

A021. Severity of Radiodermatitis in Breast Cancer Patients with Preventive Treatment with an Homeopathic/Integrative Protocol Compared with a Control Group Elio Rossi¹, Cristina Noberasco¹, Marco Picchi¹, Linda Nurra¹, Mariella Di Stefano¹

¹Homeopathic Clinic of Campo di Marte Hospital, Lucca, Italy

Background: To deal with the adverse effects of anticancer treatment, the Homeopathic Clinic of Lucca, in collaboration with the Oncology Department, has set up an Integrative Oncology Outpatient Unit in the Public Hospital Campo di Marte of Lucca (Italy).

Aims: To present the results of homeopathy and complementary integrative medicine treatment targeted towards reducing the radiodermatitis and other adverse effects of radiotherapy (RT).

Methods: This is a retrospective observational study conducted on 30 consecutive breast cancer patients undergoing radiotherapy from September 2013 to December 2018. The severity of radiodermatitis was evaluated with the Radiation Therapy Oncology Group (RTOG) scale. One group was treated with Radium bromatum 6 CH before RT, then Belladonna 6 CH after RT, and also with local application of an alkalinizing agent and Calendula ointment. The control group of patients undergoing RT without integrative treatment used only standard care – keratoplastic ointments to promote tissue repair and healing.

Results: The severity of radiodermatitis was evaluated at the beginning and at the end of the treatment; 17 patients with a homeopathic integrative protocol during RT were compared with a control group of 13 patients without treatment. Preliminary results show that 15 patients with integrative treatment had G1, 1 patient had G2 and 1 patient had G3 toxicity. In the group of patients who did not receive complementary treatments, 5 patients had G1; 2 patients G2; 3 patients G3, and finally 3 patients G4 (Mann-Whitney U-test: two-tailed significance $p \leq 0.01$).

Conclusion: The integration of evidence-based homeopathy and complementary treatments allows for an effective response to the demand from cancer patients to reduce many side effects of anti-cancer therapies, in particular radiodermatitis due to RT, as well as to improve their quality of life.

Keywords: Homeopathy, radiodermatitis, radiotherapy, integrative oncology, breast cancer patients

A022. Homeopathic Treatment of Atopic Diseases: Shortand Long-Term Results in a Cohort of 563 Atopic Adult Patients

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Background: Atopic diseases are the most common chronic conditions in childhood but, in recent decades, asthma and allergy have reached epidemic proportions among adults in most Western societies.

Aims: To study the effect of homeopathic treatment on adult patients with atopic diseases who visited the Homeopathic Clinic of Lucca (Italy) and long-term evolution of the disease over approximately an 8-year period.

Materials and Methods: Data derive from an observational longitudinal study carried out on 563 atopic adult patients who consecutively visited from 1998 to 2017: 202 (35.9%) suffered from atopic dermatitis, 204 (36.2%) from allergic rhinitis, and 157 (27.9%) from asthma. Moreover, a long-term study was conducted on a subset of 45/104 adult patients with \geq 5 years follow-up, who consecutively visited from 2006 to 2012. The study also investigated the evolution of overall symptoms in patients with a complex atopic symptomatology: that is, patients suffering with more than one atopic disease.

The outcomes were evaluated according to ORIDL (Outcome in Relation to Impact on Daily Living). Statistical evaluation was conducted via Wilcoxon's test applied to matched-pair samples, associated with a two-tailed significance test. The most frequently prescribed remedies were: in asthma, *Nat-s* and *Ars*; in allergic rhinitis, *Puls* and *Ars-i*; in atopic dermatitis, *Sulph* and *Nat-s*.

Results: 69.3% of atopic adults had moderate or major improvement (71.1% with asthma as the primary disease; 69.8% rhinitis; 67.1% dermatitis). At re-evaluation after 5–12 years, complete remission of atopic symptoms was observed in 69.6% of adult patients: dermatitis, 100%; allergic rhinitis, 59.2%; asthma, 75% (p < 0.001). Adult patients with more than one atopic disease at the first visit were completely cured in 54.3% of cases.

Conclusion: The results seem to confirm that homeopathic medicine produces positive therapeutic responses in atopic adults, and not only in paediatric atopic patients.

Keywords: Homeopathy, atopic diseases, asthma, allergic rhinitis, dermatitis, short- and long-term results

A023. Subcutaneous Isopathic Immunotherapy of Allergic Asthma in a Mouse Model of Allergic Asthma

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Background and Aims: Allergen immunotherapy is a promising potential disease-modifying treatment for allergic patients. Subcutaneous immunotherapy is more effective than sublingual immunotherapy, but subcutaneous immunotherapy is ineffective at a low dose, whereas at high doses it can result in an unacceptably prominent level of systemic reactions. Isopathy is one of the approaches of homeopathy which means employing causative agents or products of a disease to treat the same disease. In the current study, we evaluated the efficacy of subcutaneous isopathic immunotherapy with high diluted ovalbumin (HD OVA) in the treatment of OVA-induced allergic asthma in BALB/c mice.

Methods: All the experiments were conducted in accordance with the Animal Care and Use Protocol of Urmia University of Medical Sciences, Urmia, Iran. HD OVA was prepared in 6C homeopathic dilutions, 10^{-12} wt/vol, and succussed according to HPUS specifications for centesimal scale potencies. During the first week, BALB/c mice were sensitized with OVA and alum. Two weeks later, the mice received HD OVA subcutaneously on days 21, 22, 32 and on day 41 (eight hours after the last challenge) as the treatment. The mice were challenged with OVA (5%) aerosols on days 35,

38 and 41 for 20 min using an ultrasonic nebulizer, and euthanased on day 42.

Results: Our results revealed that subcutaneous isopathic immunotherapy significantly reduced lung-tissue inflammation, number of eosinophils in bronchoalveolar fluid, allergen-specific IgE and IL-4 production. It also insignificantly increased the production of TGF-β and specific regulatory T cells population against the allergen.

Conclusion: Such data suggest that subcutaneous isopathic immunotherapy may be a suitable candidate for the treatment of allergic asthma.

Keywords: Homeopathy, isopathy, asthma, allergy, immunotherapy

A024. An Assessment of a Public Health Initiative of **Homeopathy for Primary Teething**

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Background: A public health initiative, 'Homoeopathy for the Healthy Child', was undertaken focusing promotion of healthy teething by provision of home-based care through pre-identified homeopathic medicines for complaints during primary teething. The paper reports the impact on teething and episodes of diarrhoea and upper respiratory tract infection (URTI) in children.

Methods: Accredited Social Health Activists (ASHAs) were trained in child care and usage of a kit comprising six medicines: namely Calcarea phosphoricum (CP) 6x, Ferrum phosphoricum 3x, Magnesium phosphoricum 6x, Belladonna 30C, Chamomilla 30C and Podophyllum 30C. Children aged between 6 months to 1 year, and those who still had no teeth between the ages of 1 to 3 years, received CP.

Home-based care for diarrhoea, URTI and mild fever was provided using the other five medicines. Dentition pattern and diarrhoea/URTI episodes, as reported by parents to the ASHAs, were recorded for 12 months. Outcome assessed was change in dentition pattern, diarrhoea/URTI episodes, and feedback by the ASHAs.

Results: 11,426 children aged 6 months to 1 year, and 100 children aged 1-3 years with no teeth, were followed up for 12 months and dentition pattern was recorded. 0.255 proportion of children (p < 0.001) enrolled at 6 months, as compared to 0.039 enrolled at 12 months, had 6 teeth at 12 months. Incidence of diarrhoea showed progressive decline with Podophyllum or Chamomilla; likewise, URTI with Belladonna. Out of 581 ASHAs' feedback, 566 observed homeopathy as beneficial and 3 observed no effect; 12 did not respond.

Conclusion: To our knowledge, there has previously been no study reporting dentition pattern in children after using CP. This program, with regular use of CP and homebased care with homeopathy and accepted by the community, opens avenues for further validation in studies using a comparator group.

Keywords: Calcarea phosphoricum, children, dentition, diarrhea

A025. Ferrum phosphoricum D12 Treatment Affects |774A.1 and 3T3-L1 Cells Proliferation and Gene Expression of Inflammation, Oxidative Stress and Iron Metabolism-**Related Proteins**

Oskan Tasinov¹, Yoana Kiselova-Kaneva¹, Desislava Ivanova¹, Milena Pasheva¹, Deyana Vankova¹, Diana Ivanova¹ ¹Department of Biochemistry, Molecular Medicine and Nutrigenomics, Medical University "Prof. Dr. P. Stoyanov", Varna, Bulgaria

Ferrum phosphoricum (FP), the so-called "cell salt", is prescribed as a homeopathic remedy to treat the early stage of fever and inflammation in cases of cold or flu, muscle fatigue and anemia. We aimed to analyse the molecular mechanisms of action of FP D12 tablet solution in vitro, on cell proliferation and gene expression of inflammation, oxidative stress and iron metabolism-related proteins in mouse J774A.1 macrophages and 3T3-L1 pre-adipocytes.

Cell proliferation was examined using the MTT test. RT qPCR analyses followed by the $2^{-\Delta\Delta Ct}$ calculation method were performed to estimate gene expression changes. Statistical analyses were done by GraphPad Prism V6 software; p < 0.05 was considered as significant. FP effects were compared to placebo treatment (PT) and to untreated cells.

FP significantly stimulated proliferation of J774A.1 and 3T3-L1 cells, by 11% and 15% respectively, in contrast to PT in the respective concentrations.

FP vs. PT significantly induced gene expression of Ferritin FTH1 and Beta-2-Microglobulin proteins (by 8-fold and 2.5-fold respectively) and IREB2 transcription factor (by 4-fold), and induced a slight decrease in myosin 1E (by 0.4fold) gene expression levels in macrophages; whereas in preadipocytes FTH1 (by 3-fold) and IREB2 (by 15-fold) gene expression was induced. Significant stimulation of antioxidant enzymes GPX-1 (by 1.2-fold) in macrophages and GCL (by 11-fold) in pre-adipocytes by FP was observed. Significant induction in the gene expression of IL-1β (by 3.5-fold) in macrophages and of IL-6 (by 20-fold), TNFα (by 16-fold) and NOXO1 (by 17-fold) in pre-adipocytes was measured.

Results indicate that FP in D12 potency may exhibit immunostimulatory, antioxidant and increased iron uptake potential, possibly by inducing changes in gene expression

Keywords: Ferrum phosphoricum, proliferation, gene expression, macrophages, pre-adipocytes

A026. Rethinking Homeopathic Research Methodology: Why Comparative Effectiveness Research Matters

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In the last decades, a main focus of homeopathic research initiatives was experimental efficacy research to investigate specific effects of homeopathic drugs compared to placebo. Depending on inclusion and exclusion criteria, some meta-analyses have shown small specific effects of homeopathic drugs, but altogether evidence remains unreliable due to high risk of bias and methodological shortcomings.

Possible beneficial therapeutic strategies of the complex homeopathic treatment setting as a "whole medical system", such as therapeutic relationship, empathy, triggering expectations, hope, use of suggestions and metaphors, resource activation, lifestyle advice, changing conventional medication and others, were reduced to experimental comparators in the classical approach.

Homeopathic observational and outcome studies under real medical life conditions have repeatedly shown that homeopaths yield comparable effects to those of conventional therapists, but with less conventional drugs exposure and often less costs. Those "unspecific effects" are still a blind spot in the researcher's eyes but may in fact be highly beneficial for patients and a resource for the health care system.

Comparative effectiveness research (CER) strategies have been developed in the last decade to measure the extent to which an intervention, when deployed in the field in routine circumstances, does what it is intended to do for a specific population. CER methodology offers a wide range of research designs and advanced techniques, including pragmatic trials, cluster randomized trials, Bayesian approaches, observational research, and also registries. In addition, participatory stakeholder involvement is used to develop more practically relevant research questions, designs and outcomes. CER is a research strategy that would help homeopaths to better investigate and present its benefits and advantages under real life conditions, including the contribution of "unspecific effects".

Advantages and disadvantages of this approach will be presented and discussed.

Keywords: Comparative effectiveness research, homeopathy, outcome studies, pragmatic studies

A027. Cutting Edge Research – What are the Priorities for Clinical Research and Evaluation for Homeopathy to Become a Valued Part of the Integrative Medicine Model? Elizabeth Thompson¹

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Integrative Medicine is a model of healthcare which combines conventional, lifestyle and holistic approaches, informed by high-quality evidence, to improve health and wellbeing. Homeopathic researchers can struggle to get ethical approval to deliver trials of homeopathic interventions and create the kind of evidence that will allow it to become part of this growing movement for change in health care across the globe.

Dr Thompson will review the politics of homeopathic research and share her experience of designing, running and publishing a range of clinical evaluation and research studies. Within the healing model that underpins homeopathic theory and practice, the challenge remains to identify underlying mechanisms for the action homeopathic dilutions and their specific effects which we aim to identify within a placebocontrolled trial. Dr Thompson will discuss how an understanding of complexity, models of healing and local or entanglement effects, is key to designing research in complex interventions and to test the hypothesis that homeopathy can stimulate self-regulating responses to build resilience.

This presentation will contribute to an overarching question about the direction of travel needed to activate high-quality global homeopathy research programmes.

Keywords: Integrative medicine, homeopathy, trial design

A028. Safety and Efficacy of Individualised Homeopathic Treatment in Sciatica – a Phase I Pre-Post Comparison Study Aaron Ka Lun To¹, Yvonne Fok¹

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Background: Cochrane reviews in 2008 and 2016 both showed that the efficacy of NSAIDs in sciatica for pain reduction and disability were comparable to placebo. A systematic review in 2011 failed to show any long-term benefit from surgery after 1–2 years. We developed a set algorithm for individualized homeopathic treatment, which can potentially contribute to the reproducibility of the method. The algorithm was developed based on the principles of classical repertorization of local and general symptoms and differential diagnosis of 10 commonly used remedies in sciatica.

Objectives: A phase I trial of a set of algorithms for sciatica is being conducted, in which the primary objective is to compare the difference in the pain intensity of sciatica patients at baseline, day 3, day 7 and at 1 month. The secondary objectives include comparing the effects on acute, sub-acute and chronic sciatica, documenting the frequency and direction of any modification of the standardized dosage regimen, any aggravation, adverse event, or rescue medications used.

An RCT focusing first on acute sciatica will be done when these data are available, and the potential for further studies in chronic cases will be revealed. The data from the study will be able to provide more information about the effect size and dosage regimen for a more sensitive RCT design.

Methods: A prospective observational single group pre-post comparison study is being carried out from April 2018 to April 2019. The pain score pre- and post- treatment will be compared to baseline using paired *t*-test (Normal distribution) or the Wilcoxon signed-rank test (non-Normal). Comparison with relevant controls in other studies will be referred in the discussion.

Results: In the data updated in January 2019, 42 participants had been recruited and 34 (81%) of them had finished the follow up at day 7. 64.5% of them reported improvement/significant improvement. The most commonly indicated remedies were *Rhus toxicodendron*, *Colocynthis* and *Lycopodium clavatum*, representing 45.2% of all prescriptions. 16.7% of the subjects had reported an aggravation; 2.4% had reported the use of rescue medications. The final results are due in May 2019.

Keywords: Homeopathy, sciatica, individualized, algorithm

A029. Physicochemical Investigations of Homeopathic Preparations: A Systematic Review

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Objectives: The aim of our review program is to update and expand the current state of knowledge in the area of physicochemical properties of homeopathic preparations.

Methods: We identified relevant publications of sufficient reporting quality for further in-depth analysis. We reviewed all identified publications in terms of the individual experiments they describe. We extracted information

regarding methodological criteria such as blinding, randomisation, statistics, controls, sample preparation, and replications, as well as regarding experimental design and measurement methods applied. Scores were developed to identify experimental techniques with most reliable outcomes.

Results: We identified 134 publications of sufficient reporting quality to be analysed in detail. These publications described 203 experiments. Less than 25% used blinding and/ or randomisation, and about one third used adequate controls to identify specific effects of homeopathic preparations. The most promising techniques used so far are NMR relaxation, spectroscopy and electrical impedance measurements. In these three areas, several sets of replicated high-quality experiments provide evidence for specific physicochemical properties of homeopathic preparations.

Conclusions: For future experiments, we generally recommend using succussed controls, or comparing different homeopathic preparations with each other to reliably identify any specific physicochemical properties. Further in-depth analysis of the experiments is necessary to explore different hypotheses regarding a possible mode of action of potentised remedies.

Keywords: Systematic review, homeopathy, physics

A030. Use of Papaver somniferum and Arnica montana in Ultra-diluted Form to Assist in Anesthesia Recovery and as **Analgesia for Dogs having Undergone Ovariohysterectomy** David Ronald Travagin¹, Cidéli Coelho^{2,3}

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Ovariohysterectomy is one of the most frequently performed procedures in veterinary surgery. The objective was to assess the effects of using Papaver somniferum 200 cH and Arnica montana 30 cH in the recovery room and as a postoperative analgesia in dogs that had undergone an ovariohysterectomy. This study was approved by the Ethics Committee for Animal Experimentation of the Integrated University Center (No. 2124/2017).

A total of 40 dogs were considered ASA I (American Anesthesiology Association) after physical and laboratory examinations, and were randomly divided into four groups: Arnica, Papaver, hydroalcoholic and physiological solution, receiving 4 drops of each treatment every 10 minutes over a period of 1 hour. Anesthesia recovery time (in minutes), as well as the duration of the postoperative analgesia (in hours), was measured using the modified Glasgow scale. Heart rate, respiratory rate, systolic blood pressure and rectal temperature were also evaluated during the recovery period. The study was blinded. The data was analyzed using ANOVA, followed by the Tukey test, with p < 0.05 considered a statistically significant difference.

The Papaver-treated group recovered from anesthesia $(41\pm7.6 \text{ min})$ faster than the others: *Arnica* $(65.8\pm17.3 \text{ min})$, hydroalcoholic solution (68.8±15 min) and physiological solution (55.3 \pm 12.5 min); $p \le 0.05$. The Arnica group required rescue analgesia later than the others (17.8 \pm 3.6 h): *Papaver* $(6.6\pm0.9 \text{ h})$, hydroalcoholic solution $(5.1\pm1.2 \text{ h})$ and physiological solution (4.1 \pm 0.9 h); $p \le$ 0.05. There were no statistically significant differences among the other physiological parameters.

The findings of this study coincide with other studies in the literature. It was concluded that Papaver 200 cH is effective in accelerating anesthesia recovery time in dogs and that Arnica 30 cH can be an alternative in the protocol for acute pain management in these animals.

Keywords: Homeopathy, Papaver, Arnica, dogs

A031. Systematic Review of Plant-Based Homeopathic Basic Research: an Update

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Background and Aims: Plant-based test systems have been described as a useful tool for investigating possible effects of homeopathic preparations. The last reviews of this research field were published in 2009/2011. Due to recent developments in the field, an update is warranted. Publications on plant-based test systems were to be analysed with regard to publication quality, reproducibility and potential for further research.

Methods: A literature search was conducted in online databases and specific journals, including publications from 2008 to 2017 dealing with plant-based test systems in homeopathic basic research. To be included, they had to contain statistical analysis and fulfil quality criteria according to a pre-defined manuscript information score (MIS), ranging from 0-10. Publications scoring at least five points were included. They were analysed for use of adequate controls, outcome and reproducibility.

Results: 74 publications on plant-based test systems were found. 26 reached an MIS of 5 or higher. Adequate controls were used in 13 of these publications. All of them reported on specific effects of homeopathic preparations. The publication quality is still varied: a substantial number of publications (23%) did not adequately document the methods used. Four reported on replication trials. One replication trial found effects of homeopathic preparations comparable to the original study; three replication trials failed to confirm the original study but identified possible external influencing factors. Five publications described novel test systems. Eight trials used systematic negative control experiments to investigate test system stability.

Conclusions: Quality of publications has increased continuously in the period investigated. Regarding research design, future trials should implement adequate controls to identify specific effects of homeopathic preparations and include systematic negative control experiments to document test system stability. Further external and internal reproduction trials, and control of influencing factors, are needed to verify results.

Keywords: Homeopathy, plant-based test systems, review

A032. Effects of Individualized Homeopathic Intervention in Stage I Essential Hypertension: A Single-Blind Randomized, **Placebo-Controlled Trial**

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Background: Hypertension is the fourth-leading risk factor for death and disability and responsible for over 1.6 million deaths in India. Clinical case reports, observational studies and RCTs have shown homeopathy's effectiveness in managing hypertension. The results of this study will add to the evidence of effectiveness of individualized homeopathic medicine in stage I hypertension.

Material and Methods: A randomised placebo-controlled single-blind pilot trial was undertaken at five research institutes, under the auspices of the CCRH, from October 2013 to March 2018. Out of 1946 patients screened, 217 patients suffering from Stage I hypertension and fitting the inclusion criteria were randomized to receive either Homeopathy + life-style modification (H+LSM) = 116 or Placebo + LSM = 101. Patients in the verum arm were administered individualized homeopathic medicine in Q potency. The primary outcome measure to evaluate the change in systolic blood pressure (SBP) and diastolic blood pressure (DBP) were assessed every month for three months. Analysis was by intention to treat.

Results: Repeated measure ANOVA between the groups showed statistically significant differences (Wilk Lambda 0.85, F = 12.12, df = 213; p = 0.0001) in both SBP and DBP, favouring the H+LSM group. Post-hoc independent t-test showed a significant mean reduction of SBP [mean diff. 7.12; 95% CI, 4.72 to 9.53; p = 0.0001] and mean reduction in DBP [mean diff 5.76; 95% CI, 4.18 to 7.23; p = 0.0001] favouring the H+LSM group. Sulphur (n = 24), Natrum mur. (n = 21), Lycopodium (n = 16), Nux vom. (n = 12) and Phosphorus (n = 10) were the most frequently prescribed medicines.

Conclusion: Individualized homeopathy + LSM was found effective over placebo + LSM in patients suffering from Stage I hypertension. Further trials in a rigorous setting are warranted.

Keywords: Stage I hypertension, individualized homeopathy, Q potency

A033. Disperse and Dissipative Nature of Aqueous Systems - a Possible Foundation of Homeopathy?

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One of the major claims against homeopathy is that ultra-high dilutions (UHDs) of biologically active substances are identical to a pure solvent and therefore cannot possess biological activity. Thus, it is necessary to find out if UHDs differ from the solvent in their physical-chemical properties. Recently revolutionary discoveries concerning the properties of aqueous systems with "normal" concentrations of solutes, as well as of UHDs prepared from them, were made.

Contrary to the current opinion that solutions are homogenous systems, it turned out that sub-micrometer "domains", consisting of both solute and solvent molecules, emerge after dissolution of solutes in water. Upon dilution, even to ultra-high degrees, sub-micrometer structures do not disappear; on the contrary, their size usually increases.

These structures in UHDs - called "nano-associates" (NAs) by Konovalov – are negatively charged; their charge and sizes change non-monotonically with serial dilutions. Patterns of NA parameters correlate with biological effects produced by UHDs. Shielding of UHDs from ambient electromagnetic fields (EMF) prevents NA emergence in UHDs; paradoxical properties differentiating them from pure water, including biological activity, also disappear. Therefore, aqueous systems containing domains and NAs (in UHDs nonshielded from EMF) should be considered disperse systems rather than classical solutions.

Emergence of domains and NAs in them represents the process of self-organization, turning them into dissipative non-equilibrium entities. Dynamic structuring of aqueous disperse systems with charge separation in them is provided by energy supplied by environmental EMF and redox reactions, with the participation of reactive oxygen species permanently proceeding in aqueous systems.

We propose that newly discovered properties of UHDs, representing disperse systems of a "water in water" type, prove that they are basically different from a pure solvent, affirming that homeopathy has scientific foundations.

Keywords: Ultra-high dilutions, nano-associates, electromagnetic field

A034. Prevalence and Likelihood Ratio of Six Common **Objective Homeopathic Signs in Patients Responding to Muriatic medicines - Multicentre Prospective Observational Study**

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Assessment of prevalence and likelihood ratio (LR) of symptoms in responders to specific homeopathic medicines appears currently to be the best scientific method to confirm or rule out guiding indicators for such medicines.

The aim of the present study is to assess these parameters for 6 common objective homeopathic signs, believed to be indicators of muriatic medicines. Each of these signs was defined in advance. Their presence was assessed in every new consecutive patient by 8 homeopathic physicians in 3 different countries. This patient group was considered as the control population.

The target population consisted of patients responding to a muriatic homeopathic medicine. Patients were considered as responders when fulfilling all the following criteria: more than 3 months of treatment with only one homeopathic muriatic medicine: no other intervention during this period; ORIDL score +2 or higher (as assessed by the patients themselves); and the physician's impression that clinical improvement was attributable to the medicine. The same signs were assessed in this population.

Up to the time of writing, 52 responders to a muriatic medicine, 39 of whom received *Natrum-mur*, were compared to 846 controls. LR significantly higher than 1 was found in 3 of the signs (LR; 95% confidence interval): cracked lips (1.79; 1.14 to 2.82); recurrent herpes (1.96; 1.08 to 3.55); and skin eruptions on the frontal hairline (2.44; 1.42 to 4.18). In the Natrum-mur sub-group, which exhibited similar results to those overall, a fourth sign showed LR>1: dry palms (1.89; 1.08 to 3.30). The remaining 2 signs, accentuated substernal fossa and geographic tongue, could not be associated to the responding population.

Conclusions: 3 of the 6 assessed homeopathic signs could be associated to muriatic homeopathic medicines, and a fourth one specifically to Natrum muriaticum, by using a relatively simple, fast and conservative protocol.

Keywords: Likelihood ratio, objective signs, muriatic medicines

Poster Abstracts

P001. A New Area of Scientific Validation of Homeopathy: **Systems Theory**

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Homeopathy is gradually receiving scientific validation. But there is an area of science where validation is available, and which is currently not being considered.

There are remarkable parallels between the homeopathic principles of health and disease and complex systems theory. The law of cure, the value of symptoms, organisms' optimisation of their responses and other homeopathic principles can be derived from systems theory and cybernetics. These remarkable correlations provide extra scientific support for homeopathy and new ways of looking at some longestablished homeopathic principles. They can also help to lead orthodox medicine to a new understanding of health and illness based on systems science.

Keywords: Systems science, scientific validation, cybernetics

P002. Biochemical Bases of Suppression

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A recent literature review provided a number of studies with experimental information to support the phenomenon of suppression proposed by homeopathy. This phenomenon states that when a treatment is focused only towards local symptomatology, it may deepen the disease originating mental symptoms. Since the inflammation process could help understand the suppression phenomenon, this article will describe it in detail. Experimental studies reveal that inflammation is a cyclic process that does not end when the inflammatory stimulus disappears, but when specific mechanisms stop this process in order to return to homeostasis. For example, inflammatory cells can change their enzymatic systems from pro-inflammatory to antiinflammatory, producing molecules called lipoxins and resolvins. Such molecules cease inflammation, generating antiinflammatory mediators, promoting the exit of phagocytes from inflammation sites, eliminating chemokines and stimulating tissue repair. Using anti-inflammatory drugs (suppression) to stop inflammation may interfere with this physiological process, continuing with pro-inflammatory cytokine blood levels, such as IL-1, IL-6, IL-18, TNF- α and INF-γ, which activate receptors in the hypothalamus. Once these are released in the brain, they affect neural circuits that regulate behavior. The presence of these molecules decreases the availability of serotonin, dopamine and norepinephrine in the brain, increasing their re-uptake and stopping their synthesis by inducing the enzyme indoleamine 2,3-dioxygenase, which breaks tryptophan, a precursor of these amines. The events mentioned can cause significant emotional changes found in clinical depression, for instance – so much so it has been observed that the severity of depression is proportional to these cytokine levels. This mechanism could support the phenomenon whereby suppression of physical symptoms causes the appearance of mental symptoms, given that the suppression of a local inflammatory process is not solved at its origin.

Keywords: Suppression, mental symptoms, inflammation, cytokines

P003. Aspirin: From High Doses to High Dilutions - A Historical Critical Review and New Proposals

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Platelets and vessel walls interact to retain blood flow homeostasis during inflammatory conditions. Rebound effects of anti-thrombotic agents, such as prostanoids and COX inhibitors can lead to thrombosis, infarct and stroke. Aspirin has been prescribed for decades due to its powerful antiplatelet action, but it is also related to withdrawal syndrome peaks, resistance and thrombogenesis. Moreover, other paradoxical effects have also been described. A single high dose of aspirin can generate thrombus eight to ten days later; however, highly diluted aspirin can also produce the same effect in one hour, by unknown pathways, though it is known that high dilutions of aspirin can reduce PGI2 activity. Additionally, aspirin anti-thrombotic effects are also reversed by its high dilutions. Despite the fact that COX-2 selective inhibition and highly diluted aspirin have pro-thrombotic properties, the simultaneous administration of both does not further increase thrombus formation. Metabolic changes in platelets, rebound effect, delayed inhibition of COX-2 and residual endothelial aspirin accumulation are plausible hypotheses, since these patterns lead to the concept of hormesis. However, other fields of investigation, such as the characterization of nanostructures and electronic field properties of high dilutions, have not been studied yet for aspirin. Further studies involving the participation of COX-2 in macrophages, and the description of high dilution physicochemical properties and their putative relationships, are promising areas for follow-up in this subject.

Keywords: Aspirin, high dilutions, experimental models

P004. High Dilution Medicine in the Treatment of Separation Anxiety in Dogs: A Descriptive Double-Blind **Placebo-Controlled Study**

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Separation anxiety in dogs causes great distress, which leads to many clinical symptoms. Homeopathy diagnoses susceptibilities in sick individuals and treats them globally with a single medicine through the law of similarity, according to Samuel Hahnemann's unicism. The aim of this study was to quantify the behavioural changes seen in dogs treated with a high dilution medicine for separation anxiety. The demographic profiles of the dogs and their changes in cortisol levels during treatment were also to be documented. By means of a qualitative questionnaire filled in by their owners, 23 dogs diagnosed with separation anxiety were selected and repertorized according to classical homeopathy and treated with verum high dilution medicine or placebo, besides blood collection. On the 30th day, dogs were reappraised and could undergo changes in their medicines and potencies. On the 60th day a new blood sample was collected for comparison. The pharmacist was responsible for randomizing and dispensing verum medicine or placebo. In the verum group, 11 dogs (68.75%) were classified as having received effective treatment. There was no significant difference in cortisol levels between the groups (p < 0.05). The mean age of the dogs was 4 years and 7 months, and destructiveness was the most common clinical symptom. Most of the dogs were male, mixed breed, not neutered, living with a couple without children, hyper-attached to their owner and had been obtained as puppies from pet stores. Though it is possible to conclude that high-dilution medicine was able to modify dogs' behaviour, and as a feasible alternative to separation anxiety treatment, it is not possible to conclude any connection between high-dilution medicine and cortisol.

Keywords: Homeopathy, High dilution, Dogs, Behavioural Disturbance, Hyper-attachment

P005. A Randomised Controlled Trial Using Individualised Homeopathic Treatment for Modifying Anger and Blood Pressure in Patients with Essential Hypertension – Comparison Against Standard Care Treatment Leena Bagadia^{1,2}

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Background: Hypertension (HT) is the most pervasive disease worldwide, causing multiple chronic conditions without apparent symptoms. Global burden of disease is extremely high due to HT. The Framingham study tells us that about 90% of people after the age of 65 years have a lifetime risk of developing HT. The aetiology of hypertension is various and complex, involving both genetic and behavioural factors. More and more people experience increased anger, anxiety and depression brought on by globalization, cultural changes, socioeconomic changes, and stress at the work place. Anger is a critical contributing factor in essential hypertension (EHT). In our research, we tried to correlate anger with EHT and to treat anger – and thus the level of hypertension – with homeopathic simillimum.

Objectives:

- 1. To investigate the relationship between level of anger and level of hypertension.
- 2. To evaluate the safety and efficacy of homeopathic treatment on anger and thereby on blood pressure (BP) in comparison with standard care treatment for hypertension.

Methods: 300 patients with EHT were screened, 172 of whom (108 men, 64 women) were enrolled after informed, voluntary consent. They were divided into two equal groups by simple randomisation. After thorough case-taking, all patients were advised regarding DASH (Dietary Approaches to Stop Hypertension), life-style modification and anti-hypertensives, as per individual requirements. The STAXI-2 scale was applied to measure anger at the beginning and after six months' study period. One group was kept on placebo and the other on individualised homeopathic medicine. Regular follow-up was every two weeks. Data generated was analysed by SPSS v.21.

Results: Except state anger and its components, all other variables of anger, as well as systolic and diastolic BP, were remarkably reduced (p < 0.001) by homeopathy. Also, 89% of patients in the homeopathy group experienced relief in the symptoms of co-morbidities such as diabetes mellitus, rheumatoid arthritis, psoriasis, gastro-esophageal reflux disorder and chronic obstructive pulmonary disorder. Standard care with anti-hypertensives had little impact on anger or the general psychopathology of patients, and had no effect on comorbidities.

Conclusion: The patients treated with individualised homeopathic treatment showed statistically significant im-

provement in anger and hypertension, and also showed notable relief in the symptoms of co-morbidities.

Keywords: Essential hypertension, state anger, trait anger, STAXI-2

P006. 19th Century Homeopathic Materia Medica Texts Predict Source Materials Whose Physiology Influences Thyroid Activity

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Background: The homeopathic materia medica contains hundreds of thousands of observations collected over the course of centuries. It includes both clinical observations of potentized medicines and also observations of the actions of potentized medicines on healthy subjects (provings). This study was undertaken to determine the degree to which observations within the materia medica could be correlated with the physiological mechanisms for thyroid inhibiting substances in their undiluted state.

Method: Four of the most specific symptoms for iodine deficiency were selected to describe the hypothyroid state. Symptom representation for the four selected symptoms within the homeopathic materia medica was compared for two halogen inhibitors, for three substances which influence thyroid hormone target tissues, for six substances known or suspected to increase thyroid stimulating hormone or decrease thyroid hormone levels, and for eleven substances not known to inhibit thyroid activity. To avoid knowledge bias, only those compilations of materia medica whose publication dates preceded the discoveries of crucial aspects of thyroid physiology were used as source materials for investigation.

Result: Homeopathic medicines derived from 11 substances with mechanisms for inhibition of thyroid activity were more likely to exhibit selected symptoms than the medicines derived from the 11 substances without known physiological mechanisms for thyroid inhibition. The difference between groups was analyzed via the Mann-Whitney non-parametric U test and was statistically significant to p < 0.01. After observations obtained from provings alone were removed from analysis, the difference between groups of clinical symptoms remained significant to p < 0.01. Only the two halogen inhibitors of iodine (bromine and fluoric acid) and one influencer of thyroid hormone target tissue (calcium carbonate) were significantly goitrogenic.

Conclusion: With respect to thyroid inhibition, there is a significant correlation between observations recorded within the homeopathic materia medica and the purported physiological mechanisms for the corresponding undiluted substances.

Keywords: Thyroid, hypothyroidism, homeopathy, materia medica

P007. The Use of Telemedicine in Complementary Medicine Consulting: A Survey of Homeopaths and Naturopaths in Ontario, Canada

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Background and Aims: Telemedicine, defined as the use of online and telephone-based technologies in health service delivery, holds great potential for the delivery of care in both conventional biomedicine and in traditional, complementary and alternative medicine. These technologies have promise for reaching underserved populations, providing access to non-local specialists, and being convenient for

patients. This research aims to investigate the extent of, rationale for, as well as strengths and challenges associated with, telemedicine-based consulting by homeopaths and naturopathic doctors in active clinical practice.

Methods: Using a census-based approach, state-regulated homeopaths (n = 502) and naturopathic doctors (n = 1502) in Ontario, Canada were surveyed using the online Qualtrics survey tool. Survey questions captured demographic and socio-economic data of respondents as well as opinions regarding respondents' motivations behind tele-

Results: The survey is ongoing with a current response rate for the homeopathy email respondents of over 30%, and over 60% of homeopaths reporting having performed a homeopathic consultation with a patient using face-to-face online video in the past 6 months. Preliminary analysis indicates that for respondents who reported telemedicine use, the average percentage of their practice devoted to faceto-face online video was approximately 20%. In contrast, approximately 35% of naturopaths who have responded to date reported having performed a consultation with a patient using online video in the past 6 months, with approximately 10% of their practice devoted to online video consultations.

Conclusions: Face-to-face online video appears to be used by a majority of homeopaths in Ontario, Canada. Ontario homeopaths are nearly twice as likely to engage in online video consultations as naturopaths. Future analysis of the data will explore the motivations behind telemedicine use amongst homeopaths and naturopaths in Ontario as well as any demographic or socio-economic factors influencing telemedicine usage.

Keywords: Homeopathy, naturopathy, telemedicine, survey

P008. Physical-Chemical Analysis of Different Homeopathic Medicines Using Solvatochromic Dyes as Indicators of **Solvent Dipole Moment Changes**

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Introduction: Homeopathy is a recognized science throughout the world, but the lack of knowledge about its mechanism of action still renders it controversial. Currently, several theories are proposed, one of which is that specific electromagnetic fields of the solvents can convey information to biological systems, from the diluted raw material. Recently, the use of solvatochromic dyes has been proposed to identify changes in the solvent dipole moment, along successive dilutions, by solute interference. The present research proposes the evaluation of the dielectric activity of homeopathic drugs by means of the absorbance curve obtained by different solvatochromic dyes, using different potencies.

Methods: Samples of Antimonium crudum, Phosphorus, Zincum metallicum and Silicea terra, in potencies ranging from 6 to 200 cH (as well as the controls: pure water, dynamized pure water and vehicle [30% ethanol solution]), were analyzed by the solvatochromic dye method to establish an absorbance curve. The dyes used were: ET33, BDN and Violet Methylene. The analysis was performed in a FEMTO™ spectrophotometer (Brazil), with high sensitivity for optical density variations and with a wavelength scan of at least 1 nm. All samples were analyzed in triplicate and the results

were evaluated by one-way ANOVA and Tukey's post-test, with p < 0.05.

Results: Preliminary data from tested samples of Antimonium crudum 120 cH and Phosphorus 30 cH showed an increase in the peak of absorbance of Methylene Violet, but not the other dyes. On the other hand, only Antimonium crudum 30 cH showed an increase in the absorbance of the ET33 dye. The analyses of other samples, potencies and dyes are still in progress.

Conclusions: Preliminary results indicate that variation of different solvatochromic dyes might be useful in the characterization of different potencies of homeopathic medicines, according to changes in the peak of absorbance obtained in the visible light spectrum.

Keywords: Ultradilutions, homeopathy, spectrophotometry, electrical resonance

P009. Physico-Chemical Characterization of High Dilutions of Symphytum officinale and Therapeutic Effect in Hepatic and Osteosarcoma Cells

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Background and Aim: Symphytum officinale (SO) root and leaf extracts are used as a remedy for bone fracture healing, anti-inflammation, and also prescribed clinically in high dilution as a homeopathic medicine. These extracts have lycopsamine, rosmarinic acid, symphytine and coumaric acid as major pyrrolizidine alkaloids. The objective of this study was to characterize SO mother tincture (SOMT), 6c, 30c and 200c, and to study biological responses with hepatic epithelial WRL-68 and osteosarcoma Saos-2 cells.

Methods: Physico-chemical characterization of SO were studied with high resolution liquid chromatogram mass spectrometer (HRLCMS), nuclear magnetic resonance spectroscopy (NMR), Fourier transform infrared spectroscopy, scanning electron microscopy and transmission electron microscopy (TEM). In-vitro drug efficacy was studied in WRL-68 and Saos-2 cells using a confocal microscope, MTT cell viability assay and flow cytometer techniques with commercially available SOMT, 6c, 30c and 200c.

Results: Lycopsamine mass peak of 300.47 Da, symphytine 381.075 Da, symviridine 382.45 Da and other pyrrolizidine fragments were detected using HRLCMS for SOMT. 6c. and 30c. Chemical shifts of 58.49ppm and 18.47ppm in 13C NMR confirm the presence of carbonyl, alkyl, amines, alkanes and alcohol functional groups. Silicates and micro-elements (K, Na, Mg, P, S) were detected in SO samples using high resolution TEM. Hepatotoxicity and anti-proliferative effects of SOMT were observed in WRL-68 and Saos-2 cells, whereas cell proliferation and hormesis were confirmed by MTT assay when treated with 6c to 200c for 48hrs. Morphology of Saos-2 and WRL-68 cells showed cytoskeletal disorientation with intact plasma membrane and nucleus with SOMT, 6c, 30c after 24hrs in confocal micrographs.

Conclusions: SO retained lycopsamine, symviridine and other pyrrolizidine alkaloids in high dilution up to 30c potency. This corresponds to silica encapsulation of starting material as shown in TEM micrographs. Significant proliferation of Saos-2 cells treated with SOMT to 200c confirms SO efficacy for bone healing.

Keywords: Symphytum officinale, HRLCMS, high dilution, lycopsamine, TEM

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P010. Homeopathic Immunotherapy against Cancer Eneida Da Lozzo¹, Edvaldo da Silva Trindade², Carolina De Oliveira², Dorly de Buchi²

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Introduction: Our research team at Federal University has studied, in vitro and in vivo, cancer cells treated with homeopathy in the last 20 years. After using different products and analysing the different results carefully, we arrived at two complexes produced with homeopathic techniques, coded as M1 and M8. The results obtained using these two products were surprising and some were published in scientific journals with good impact.

Methods and Results: The most appropriate and diverse methodology was used, with several controls: Confocal, Histochemistry, Electron Microscopy, Flow Cytometry, Slide Scanner, Matrigel matrix invasion, ImageJ software, etc. Our studies, in vitro and in vivo, have demonstrated that the medicines M1 and M8: prevented lung and subcutaneous melanoma growth; decreased angiogenesis inside tumors (p < 0.01); decreased some extracellular matrix molecules, such as perlecan and hyaluronic acid, decreasing metastasis (in Transwell plates, p < 0.01); activated macrophages, that can activate other cells in the immune system as well as endothelial cells and fibroblasts: modulated cytokines such as TNF α , IFN γ and IL10; increased not only the differentiation of NK cells (in flow cytometer, p < 0.001) but also the cytotoxicity of NK cells (p < 0.05); modulated reactive oxygen species (ROS) and nitric oxide (NO) production.

Conclusions: M1 and M8 are homeopathic complex medicines with immunomodulatory properties, without toxicity or mutagenic effects. This homeopathic immunotherapy can gently restore the immune system to recognize tumor cells; thus, they can be used to help in all cancer immunephenotypes without acting on a specific molecular target and without toxicity, since the self-healing is stimulated through the immune system. However, the absence of clinical trials has limited their extensive use in cancer immunotherapy, despite the promising results in vitro as well as in vivo. Moreover, because in homeopathy we do not have a molecule to track, there is an impediment to further progress with these medicines without greater understanding of their physiological mechanism of action.

Keywords: Cancer, immunotherapy, homeopathic complexes, immune system

P011. Homeopathic Treatment of Psoriasis: A Case Series Francisco Eizayaga¹, Carolina Aguilar¹, Adriana Ceballos¹ ¹Department of Homeopathy, Universidad Maimonides, Buenos Aires, Argentina

Background and Aims: Psoriasis is a chronic disease frequently treated in homeopathic practice. However, there is only one prospective uncontrolled multi-centric study published, with 2 years of follow-up. The aim of this paper is to evaluate retrospectively the treatment results of patients with psoriasis in the Department of Homeopathy of Universidad Maimonides.

Methods: The totality of cases of psoriasis who attended the Homeopathic clinic was searched. Forms were created and examined with EpiInfo software. Evaluated outcomes: type of psoriasis, severity, presence of arthritic psoriasis, prescription criteria, homeopathic remedy used, skin outcome, presence of aggravation, outcome of psoriatic arthritis, safety of the treatment. Follow-up was evaluated for 1 year. Patients without at least 1 follow-up visit were excluded from analysis.

Results: A total of 94 patients presented a clinical record of psoriasis: 49 returned once for follow-up and 18 had follow-up visits up to and including one year. Plaque psoriasis was 86% and guttate psoriasis represented 14%. Psoriatic arthritis was present in 15% of the cases. The predominant criteria for prescription was the totality of symptoms and the most frequently prescribed potency the 6 cH. A small or large improvement in psoriasis was observed in 57% of the patients at the second consultation and in 64.7% of the patients after 1 year of treatment. The most frequently used remedies were Sulphur, Lycopodium, Pulsatilla and Arsenicum album, but the variation was high. Four of 6 patients with arthritis reported to be better at the second consultation, but only 2 of 6 after one year of treatment. No serious adverse events were observed.

Conclusions: Homeopathic treatment of psoriasis, including psoriatic arthritis, appears to be safe and to have some positive outcome. Prospective controlled trials should aim to verify these results.

Keywords: Homeopathy, psoriasis, psoriatic arthritis

P012. Efficacy of Homeopathic Herd Health Management in **Antibiotic Resistant Dairy Cattle in Northern Spain**

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Background: Milk yield in dairy farms worldwide has improved due to advances in genetics, feeding and cattle handling. Maximum yields lead to stress and immunosuppression of the animal, having to rely heavily on antibiotics to preserve health. Consequently, there is an ever-increasing level of antibiotic resistance and chronic disease in dairy

Objectives: To demonstrate the effectiveness of homeopathy-based treatments in dairy farms with above average disease incidence and antibiotic resistance.

Study Design: Longitudinal, observational, and prospective.

Methods: The study was conducted in three Holstein farms (average: 25 animals/farm) in semi-extensive systems, fed concentrated feed, silage and pasture. The measured variable was SCC (somatic cell count per millilitre), taken from the milk tank every 48 hr. and analysed with SPSS software. The cut-off number for an acceptable sample was

From 2013 to 2015 the animals were treated individually with classical homeopathy, and from 2015 until 2017 a preventative homeopathy herd health program was implemented. Choice of treatment program was based on disease aetiology in each herd, blood work, and SCC.

Treatment administration was the Plus Method (3 pills/125 ml of mineral water) of 6, 30 or 200 cH potency. Administration route was P.O. or in concentrated feed.

Results: Prior to homeopathy treatment (2007–2013), only 22%, 25% and 27% of the samples from each farm had an SCC below 250. Once homeopathy treatment was started (2013-2017), these farms reached 66%, 56% and 46% (respectively) of days with SCC below 250.

Main Limitations: Lack of proper assessment by the farmer and sub-optimal nutrition.

Conclusions: When comparing treatments in dairy farms, homeopathy is more effective at keeping SCC below the 250 threshold.

Keywords: Dairy, homeopathy, SCC, antibiotic resistance

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P013. Physicochemical Characterization of Dynamized Solid

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Homeopathic medicine is defined as the pharmaceutical form obtained by the method of dilutions followed by successive succussions or crushing. Clinical homeopathic results have proven the efficacy of these drugs by different experimental models. However, with regard to the dynamics of solid systems, scientific knowledge is still very undeveloped.

In this context, in 2013, a Multicentric Project (Brazil-Italy) was started with the objective of expanding the studies of this system using dynamized solid systems prepared with metallic zinc in lactose (ZnMet). In this way, the present work evaluated the physical-chemical and structural changes resulting from the trituration process. The X-ray diffraction results indicated no changes in the crystalline structure of the lactose after the grinding process and also the presence of the zinc signal in the first potency (ZnMet 1dH).

Evaluation of differential exploratory calorimetry data shows that both the presence of zinc and the dynamization process alter the enthalpy values of the solid system as well as the dehydration temperature. In the Raman spectroscopy analysis, the amplitude and area of ZnMet (3 dH and 6 dH) samples were observed, especially in the region with the highest truss vibration (from 200 cm⁻¹ to 500 cm⁻¹).

In the infrared spectroscopy analyses, a decrease in signal intensity due to the dynamization process and the presence of zinc was observed, suggesting the formation of a complex between the metal and lactose. The scanning electron microscopy evaluation showed small particles with rough appearance on the lactose surface, indicating the adsorption of zinc to lactose.

This set of results suggests that the presence of zinc and the grinding process alter the enthalpy, polarization and vibration of chemical bonds of the dynamized solid system, and these methodologies are sensitive enough to characterize these homeopathic systems.

Keywords: Physical-chemistry, Homeopathy, Zinc, lactose, dynamization

P014. Feasibility of Homeopathic Treatment for Symptom **Reduction in an Integrative Oncology Service**

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Background: Homeopathy has the potential to reduce symptoms related to cancer treatment. The present study examined the feasibility of a homeopathic consultation and treatment program, provided as part of an integrative oncology service.

Methods: The electronic medical files of patients undergoing a homeopathic consultation in an integrative oncology service clinic were examined retrospectively. Adherence to the homeopathic treatment regimen and perceived response to the treatment were evaluated.

Results: The files of 124 patients (34 males, 90 females) were examined, of which two-thirds reported acquiring and self-administering the homeopathic remedy as prescribed, and nearly three-quarters reporting a beneficial effect. Adherence to the homeopathic treatment regimen was greatest among patients attending a second visit, as opposed to having only telephone/e-mail follow-up (p < 0.005). An association was found between a perceived beneficial effect of treatment with attending a follow-up visit (p = 0.04), female gender (p = 0.02), younger age (p = 0.048), diagnosis of breast cancer (p = 0.014), and current radiation treatment (vs. chemotherapy; p = 0.003). Patients reporting chemotherapy-induced peripheral neuropathy were also more likely to report a beneficial effect (p = 0.004), as were female patients reporting hot flashes (p = 0.005) and those referred by an oncologist (p = 0.046). No adverse effects were attributed to the homeopathic treatment.

Conclusions: Homeopathy can be successfully incorporated within a supportive care integrative oncology service. In addition to demographic and cancer-related characteristics, as well as symptoms, patients attending a second visit (vs. only telephone/e-mail follow-up) were more likely to adhere to and perceive a beneficial effect from the homeopathic regimen.

Keywords: Homeopathy, oncology service, symptom reduction

P015. Individualized Homeopathic Treatment in Women with Recurrent Cystitis: A Retrospective Case Series

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Background: Approximately 13% of women develop recurrent urinary tract infections (rUTI) in their lifetime. Most clinicians are faced with repeated and long-term administration of broad-spectrum antimicrobial agents. This leads, however, to increased presence of drug-resistant bacteria and the disruption of normal levels of intestinal and vaginal flora and might lead to persistent infections and/or damage of the urinary tract. A new strategy is therefore warranted.

Methods:

Design: Case series of all patients treated with individualised homeopathy (iHOM) for rUTI at the Institute of Complementary Medicine, IKOM, at the University of Bern, Switzerland.

Subjects: Four females, aged 30–79.

Observation time: November 2013 to August 2018.

Analysis: Frequency of UTI and of antibiotic (AB) treatment were documented in the patients' files. Additionally, treatment outcomes were assessed retrospectively in a validated questionnaire on Impact on Daily Living (ORIDL).

Results: The frequency of UTI and the need for AB reduced from at least monthly to less than 3 times a year. Three of the four women had no cystitis and related intake of AB for more than 2 years. In two of these patients, a relapse of symptoms could be treated efficiently with a repetition of the same homeopathic remedy. The subjective outcome assessments of all patients was reported positive. Three patients appraised major improvement for the main complaint.

Discussion: The treatment options for rUTI are limited and not always successful. Within this case series a new approach, iHOM, results in a positive outcome, both objectively (by reducing the frequency of UTI and the amount of AB courses) and subjectively as per patients' assessments.

Conclusion: The evolution of the disease in the analysed patients suggests that iHOM might be a reasonable approach for the treatment of rUTI. It should be further investigated with prospective open-label and controlled studies.

Keywords: Urinary tract infections, antibiotic resistance

P016. Analysing the Conflict between Biomedicine and Homeopathy

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The broad objective of this research project is to understand conflict and conflict management and to apply that knowledge to the conflict between biomedicine and homeopathy. My presentation examines a variety of theoretical frameworks around conflict. Initially examining conflict as a topic and its historical role in war and politics alongside new strategies used currently, I bring to light an understanding of conflict in general. Using the perspective of Gandhi's non-violent resistance, Clausewitz's strategy on war, Machiavelli's political strategic considerations and Sun Tzu's Art of War, I disclose how conflict has been managed historically, what strategies have been used to succeed and what mistakes have resulted in defeat. I have chosen to study military and political conflict strategies because biomedicine currently has the power to marginalise other therapeutic approaches, such as homeopathy, using strategies usually reserved for war and politics.

Through the available body of information from the NHMRC report, I will disclose how orthodox medicine is using its dominant position to write reports and make claims as a mechanism of exclusion, a strategic plan to marginalise homeopathy. I will look at the strategies used by orthodox medicine to gain dominance and the deficiency of homeopathy's approach culminating in its lost position.

Homeopathy fundamentally challenges the implicit assumption of biomedicine (that disease is to be fought) with its intrinsic principle of symptom similarity. Ironically, vaccination sits as a centerpiece expression of this principle. From my own experience as a homeopath I suggest the Law of Similars as a mechanism for conflict resolution.

Conclusions drawn from this investigation may provide novel approaches to conflict resolution and a theoretical framework where rapprochement between biomedicine and homeopathy may be possible.

Keywords: Conflict, strategy, biomedicine, homeopathy, rapprochement

P017. Understanding the Extent and Diversity of Homeopathic Practice in Australia

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The broad objective of this project is to understand the extent and diversity of professional homeopathic practice in Australia. A snapshot of clinical practice taken over an eightweek period is reported. The demographics of patients, conditions treated, and remedy prescriptions are studied. This pilot study is approved through the Ethics Committee process. Informed consent is obtained by both the homeopath and the patients in their practices. The data tool used to collect patient data, HomeoStats, is an online interface allowing homeopaths to enter limited information about their patients for the study. Data added included patients': age, gender, ethnicity, place of birth and current residence, presenting condition(s) as defined by the International Classification of Primary Care-II, and remedy and potency prescribed. All the patient data is deidentified at the point of collection. The population of homeopaths in Australia is an unknown number. The industry is unregulated. However, the Australian Register of Homoeopaths (ARoH) is a self-regulating body defining minimum standard of practice for homeopaths in Australia. Registration

with ARoH is used as an essential requirement for homeopaths to participate in this study. The total population of ARoH members is 513 at the start of the survey. The project's secondary aims include practitioner education and research upskilling through the use of Practitioner Based Research Networks. The primary aim of these networks is to engage practitioners to increase their skills in research and transfer learning into clinical practice, contributing to an increase in capacity for homeopathy in Australia.

Keywords: Clinical practice, homeopathy survey, demographics, Australia, health conditions

P018. Improving Decision-Making in Homeopathic Clinical Practice

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Background: Decision-making in homeopathic practice is a highly complex process. Although guidelines for a successful prescription have been set, homeopathic practitioners consciously and unconsciously make use of heuristics ('rules of thumb' /mental shortcuts) in order to reduce this complexity and reach a remedy decision. Whilst biases affecting the reliability of repertory rubrics are now better understood, biases associated with the actual decision-making process are still under-researched.

Objectives:

- To identify and explain the main biases affecting decision making in homeopathic practice.
- To illustrate the role that decision support systems can play in reducing these biases.

Methods: The literature on heuristics and biases that can affect decision-making was searched. Those deemed relevant for decision-making in homeopathic practice were identified. The role that a clinical decision support system (Vithoulkas Compass) can play in minimizing the identified biases was assessed.

Outcomes: The role and implications of the availability heuristic, the representativeness heuristic, the anchoring heuristic as well as confirmation bias will be explained. Repertory software and decision support systems are important tools for improving the quality of homeopathic decisionmaking. The most important proposed and illustrated innovations are:

- Prompts about potential biases during the symptom selection process.
- Visualization of the prevalence (base rate) of the selected symptoms in the general patient population during the decision process.
- Prompts during the differential diagnosis not to exclude a particular remedy in the absence of particular keynote symptoms.
- 4. Delaying the shortlisting of potentially indicated remedies, and to base the shortlist on multiple analytical strategies.

Conclusions: The Vithoulkas Compass online homeopathic platform aims to integrate the latest knowledge on reducing biases in clinical decision-making. Optimal decision-making involves blending the useful aspects of heuristics with a slow thinking process that balances the tendency to 'jump to the wrong conclusions' as and when needed.

Keywords: Decision-making, heuristic, bias, Vithoulkas Compass

P019. Wound Healing Following Tooth Extraction and Arnica montana C30

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Background: Pursuing suggestions from empirical medicine, a pilot study in 2015 investigated and described effects of Arnica montana C30 on wound healing. 23 subjects received the verum, 23 received placebo. One day after tooth extraction, 15 verum and 10 placebo-treated subjects were pain-free, 13 and 5 respectively showed smooth (versus jagged) wound edges and 20 and 22 presented pink (versus livid) wound edges. After one week, all 23 subjects in the verum group and 21 in the control group were pain-free, none had post-operative bleeding, 20 and 17 showed smooth and 19 and 6 showed pink wound edges. Although statistically non-significant, this outcome indicated some beneficiary effect on wound healing of Arnica C30.

Objective: To replicate the pilot study on Arnica C30 and the course of healing after tooth extraction.

Methods: The study design was unicentric, controlled, randomised, double-blind. All 117 recruited subjects completed their participation: 58 received Arnica C30, 59 received non-medicinal globuli. We recorded pain, bleeding, and wound status postoperatively on day 2 and day 7.

Results: On day 2, 42 verum and 40 placebo-treated subjects were pain-free, 50 and 42 respectively had no postoperative bleeding, 28 and 24 showed smooth and 8 and 4 presented pink wound edges. After one week, all subjects were pain-free and had no post-operative bleeding, 40 and 43 showed smooth and 26 and 22 pink wound edges. None of these trends was significant (p>0.05). On pooling the results of this and the pilot study, the only statistically significant trend was on pink wound edges (p < 0.01).

Conclusion: The trends found in the present study are largely in agreement with those of the pilot study. Further research on the effects of Arnica montana C30 thus appears worthwhile.

Keywords: Tooth extraction, wound healing, Arnica montana, high potency

P020. Emotional and Mental Causes as Catalysts in the **Development of Cancer**

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Substances that cause cancer have been identified both by studies in experimental animals and by epidemiological analysis of cancer frequencies in human populations (e.g. the high incidence of lung cancer among cigarette smokers). Since the development of malignancy is a complex multi-step process, many factors may affect the likelihood that cancer will develop, and it is overly simplistic to speak of single causes of most cancers. Nonetheless, many agents, including radiation, chemicals and viruses, have been found to induce cancer in both experimental animals and humans.

However, all the persons exposed to potential carcinogens do not necessarily develop cancer. Often it has been observed that some mental or emotional traumas act as trigger factor or act as catalysts in development of cancer. The present research focuses on studying cancer cases by evaluating the time frame of the mental or emotional traumas that patients may have suffered and the time duration in

which cancer developed. 100 patients have been studied from the time of an emotionally or mentally traumatic episode and any development of cancer within 0-6 months, 0-12 months or 0-24 months.

Appropriate non-parametric tests are being applied to analyse the data.

The context of the research is to widen the possibility of homeopathic treatment in cancer. Various homeopathic medicines are known to treat effects of mental trauma and its ailments. It can be a valuable tool for homeopaths to utilize the data and further enhance the management of cancer with homeopathy.

Keywords: Cancer, emotional causes, homeopathic management

P021. Homeopathic Preparations in the Low Potency Range Studied by Means of Pattern Formation in Evaporating **Droplets: Screening Experiments, Sample-Differentiation** and Repeatability

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Background and Aims: Here we propose, for the first time, the droplet evaporation method (DEM) as a tool to distinguish low potencies prepared from different substances on a qualitative and quantitative basis. Low potencies ($\leq 6x$) contain measurable quantities of the starting substance and so give the possibility to study the changes this very substance undergoes in the course of successive potentization

Materials and Methods: The experimentation consisted of: (i) screening of 1x-6x potencies deriving from 19 different substances of mineral, vegetal, and animal origin; (ii) experiments aiming at the differentiation of homeopathic preparations at the same potency level prepared from 4 prechosen substances (Echinacea, Baptisia, Luffa, and Spongia) in the potency range 2x-6x; and (iii) control experiments. The DEM experimental protocol consisted of the evaporation of droplets of the analyzed potency per se, placed on microscope slides and under controlled conditions. The resulting patterns were photographed. Images from main and control experiments (ii and iii; in total 2331 images) were evaluated by measuring their grey level distribution and texture.

Results: Potencies of mineral origin showed the greatest form variety, whereas potencies of vegetal origin in the potency range 2x-4x created fractal patterns, probably in the course of diffusion-limited aggregation. The differentiation of homeopathic preparations at the same potency level prepared from 4 pre-chosen substances (Echinacea, Baptisia, Luffa, and Spongia) was possible in the potency range 2x-4x, whereas patterns from higher potencies could no longer be differentiated and resembled the pattern of pure solute. The control experiments showed reasonable experimental model stability.

Conclusions: DEM seems to represent a promising tool for further studies on homeopathic preparations in the low potency range: for instance, comparison of potencies versus dilutions, or qualitative studies on complex homeopathic preparations regarding the influences of single compounds on the DEM patterns.

Keywords: Evaporation patterns, homeopathy, low potencies

P022. Homeopathy in the NHS (National Health Service): Diluted but Active

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Background: Despite being used satisfactorily by millions of people worldwide for a range of conditions, and the homeopathy community's efforts to integrate homeopathy into NHS services, homeopathy provision has been declining.

Aim: A pragmatic investigation of the integration of homeopathy in the UK NHS.

Method: A nationwide postal survey among 144 members of the Faculty of Homeopathy mapped demographic data and integration of homeopathy services in the NHS, building on a Canadian integration model proposed by Boon in 2004. To enable a comprehensive understanding, 10 semistructured interviews explored homeopaths' strategies to integrate homeopathy successfully into NHS services.

Results: A sample of 72 respondents revealed that 27 were actively offering homeopathy treatment in their NHS service. According to the continuum proposed by Boon, UK services integrating homeopathy treatment are characterised as collaborative and multidisciplinary. Seven profiles of homeopathic providers in the NHS could be distinguished. In the interviews, several suggestions were put forward to restore the badly damaged image of homeopathy. The interviewees disagreed about whether integration was the preferred strategy to reach this goal, or even whether integration was desirable at all, but the accreditation of homeopathy within the healthcare system was deemed vital for the survival of homeopathy, even for the success of private practices. A lack of resources and the dwindling numbers of newly trained homeopathy practitioners were mentioned as a matter of concern. A major frustration was the negation of existing evidence for homeopathy, leaving homeopaths questioning what kind of evidence – from fundamental research or from outcome studies - would be the best way forward.

Conclusion: Despite positive results regarding the integration of homeopathic services in the NHS, the information disclosed in the interviews revealed a concern about the survival of homeopathy.

Keywords: Health service, homeopathy, integration

P023. Symptom Severity and Functional Status in Patients with Joint Pain, Back Pain, Headache, and Cough: A 10-year Retrospective Analysis of The Swaziland Homeopathy Project

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Background and Aims: Over the past 10 years, the Swaziland Homeopathy Project has treated 9,866 patients in Eswatini and Mozambique in Southern Africa. The patients ranged in age from under 10 to over 79 years and 79% were female. Most lived in rural areas. The Project practices classical homeopathy.

Research Questions: What are the most common presenting symptoms? What are the characteristics of the patients reporting these symptoms? Do these patients report improvement in their symptom intensity and functional scores?

Method: We conducted a retrospective analysis using de-identified chart data. We collapsed similar symptoms into categories and ascertained the most frequent presenting complaints. Patients reported symptom severity on a visual analogue scale and overall function on a modified Karnofsky

Performance Scale Index at each visit. We extracted the scores as reported on initial and follow-up visits.

Results: The most common symptoms treated were joint pain, back pain, headache, and cough. These four symptoms were reported at 33,649 visits, 50% of which have at least one follow-up. Of the patients seen for each of these complaints, 11–19% were male and 81–89% were female. Symptom severity improved in 49–63% of patients, with the complaint of headache showing the greatest improvement. Approximately 10% of patients reported a worsening of symptom severity. Regarding the functional scale, 41–49% of patients reported improvement, while 11% reported deterioration in their overall function regardless the symptom. Those who were treated for cough reported the greatest functional improvement.

Future Direction: In this retrospective chart analysis, patients reported improvement in their symptoms. Patients complaining of headache and cough possibly incurred the greatest benefit, so these symptoms will be the focus of the next phase. The future prospective study will investigate statistical significance and attempt to differentiate improvement beyond that expected from placebo.

Keywords: Symptoms, retrospective, pain, cough, Africa

P024. Usage Protocol Study of *Calendula officinalis* compared to Chlorhexidine in Oral Hygiene of Patients Admitted in the Intensive Care Unit

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Background: Pneumonia is defined as the presence of pulmonary infiltrate of infectious origin, with the onset of fever, purulent sputum, leukocytosis and oxygenation reduction. Ventilation-associated pneumonia (VAP) is the one that occurs after 48 h of endotracheal intubation and affects 9–27% of patients in the Intensive Care Unit (ICU). In order to prevent patients from developing VAP, intervention protocols were drafted. One of those was oral hygiene using chlorhexidine (CLX) as mouthwash at the concentration of 0.2% or 2%, the latter being more effective. Depending on the length of use and the concentration increase, the bacteria will develop resistance to CLX, while some studies show the use of Calendula officinalis (Cal off) as beneficial.

Aims: The present study aims to develop pharmaceutic gel formulations, using Cal off in 1 DH potency and CLX in 2% concentration, for further evaluation of their physicochemical, microbiological and biological response characteristics in ICU patients.

Methods: The two formulations were prepared according to the Brazilian Pharmacopeia (FB) 5th ed. and the Brazilian Homeopathic Pharmacopeia (FHB) 3rd ed. Stability studies were performed during their storage in a greenhouse, at room temperature or in a refrigerator, and according to appropriate standards.

Results and Conclusions: Preliminary results show the mother tincture of Calendula presents all the quality parameters required for use in homeopathic medicine. The formulations developed showed a pH drop in all gels as well as a viscosity decrease for gels stored in the greenhouse for 30 days. The gels stored at room temperature did not have alterations in their organoleptic characteristics. The gels were applied in 8 ICU patients and it was observed that the treatment with Calendula gel was more effective, as it inhibited microbial growth in 50% of the patients, after 3 sample collections. The study is underway with an expected duration of 6 months.

Keywords: Intensive care unit, ventilator-associated pneumonia, chlorhexidine, Calendula officinalis, homeopathy

P025. In-vitro Anti-fungal Activity of Aloysia polystachya Essential Oil in High Dilution on Aspergillus flavus Isolated from the Brazil Nut (Bertholletia excelsa)

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Background: Bertholletia excelsa, Brazil nut, has significant participation in the food and cosmetic industry. However, contamination by Aspergillus flavus, an aflatoxinproducing fungus that causes post-harvest rot, is a serious impediment to its commercialization. Substances of plant origin are an important therapeutic resource and the dynamization of essential oils is a safe and efficient pharmacotechnical technique. Aloysia polystachya is a plant native to South America whose essential oil has a considerable biocidal

Aim: To determine the ability of the original and dynamized essential oil of A. polystachya to inhibit the invitro multiplication of the fungus A. flavus isolated from Brazil nuts.

Methods: The essential oil of A. polystachya, obtained by hydro-distillation, was diluted with Tween 80 (1%) and then dynamized. The activity of the original and dynamized essential oils of A. polystachya was evaluated by the Minimum Inhibitory Concentration (MIC) and Minimum Fungicidal Concentration (MFC) methods. The vehicle control was performed and resazurin was used for the reading. The analyses were performed in triplicate and the results were submitted to ANOVA, the means of the treatments being compared by the Scott-Knott test (p < 0.05).

Results: The original essential oil of A. polystachya presented an MIC of 1.56 μg.mL⁻¹, differing statistically from the MIC of the dynamized form, which was $0.01 \mu g.mL^{-1}$. In the MFC evaluation, both treatments presented fungistatic activity against A. flavus.

Conclusions: The highly diluted essential oil of A. polystachya presented significant fungistatic activity against A. flavus and, therefore, may be a promising resource in the control of post-harvest contamination in Brazil nuts.

Keywords: Aloysia polystachya, Aspergillus flavus, Bertholletia excelsa, dynamization, anti-fungal activity

P026. Use of Homeopathic Complex in the Control of Dairy **Cattle Ticks**

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Background: Rhipicephalus (Boophilus) microplus parasitism causes large losses in bovine herds, and its control by means of synthetic carrapaticides causes resistance problems, as well as the risk of residues in food and environment.

Aim: To evaluate the effectiveness of a homeopathic complex in the control of the natural infestation of lactating dairy cows and its in vitro effect on engorged females.

Methods: The tests were carried out in two dairy farms between May and October 2018. One farm is certified organic, with 70 animals, and the other uses the conventional production model, with 16 animals. The homeopathic formulation was composed of Staphysagria 3 DH, Cina 6 CH, Sulphur 6 CH and auto-isotherapic of tick 30 CH. The bovine females received orally 10 grams per day of the homeopathic complex, incorporated into sucrose. The outcome parameters, as designated by the producers, were degree of infestation (%) and physical appearance of the parasites. For in vitro evaluation engorged females of Rhipicephalus (Boophilus) microplus, collected from naturally infested animals, were submitted to the immersion test.

Results: According to the producers' designation, in both farms there was a mean reduction of infestation by 80% in the treatment period and alteration in the coloration of the lighter parasites, with a more wrinkled appearance. In the in vitro test, the homeopathic complex showed an efficacy of 13% and 55%, in the organic and conventional farm respectively.

Conclusion: The homeopathic complex presented effective control in the natural infestation of ticks in dairy cows of organic and conventional farms.

Keywords: Rhipicephalus microplus, high dilution, organic

P027. The Homeopathic Approach to Treatment of Polycystic Ovarian Syndrome in a Rural Set-up Sujata Naik¹

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Background: Polycystic Ovarian Syndrome (PCOS) is a complex, chronic lifestyle-linked disorder associated with hyperandrogenism, oligo-anovulation and polycystic ovarian morphology.

According to Indian Council of Medical Research, one out of ten women in India suffers from PCOS and the number is increasing alarmingly, even in rural areas. Changing dietary habits (consumption of fatty, processed foods) and sedentary lifestyles result in decreased metabolism, insulin resistance and obesity – factors contributing to menstrual irregularities.

Aim: The objective of the study was to assess the efficacy of homeopathy as a treatment option for PCOS.

Methods: A retrospective observational study of 72 patients, who were diagnosed cases of PCOS, was carried out at a community hospital in rural Maharashtra.

In a mass setting with a large number of patients from poor socio-economic strata, presenting with common symptoms of PCOS, there was paucity of characteristic symptoms. Therefore, the keynote method of prescribing was employed. The data regarding each patient's presenting symptoms was noted. The protocol followed in this study was formed based on totality of common symptoms of PCOS (irregular menses, obesity, secondary hirsutism, lethargy, acne, infertility). One characteristic symptom (keynote) was selected as a differentiating rubric to choose the most similar remedy from the ones derived.

Each patient's monthly progress and clinical outcomes, up to one year of starting therapy, were noted.

Results: Out of common symptoms of PCOS, lethargy, loss of general feeling of well-being and irregular menses

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were the first ones to be ameliorated, which indicates the correct direction of homeopathic action.

Conclusion: Homeopathy as a treatment modality may add substantial value to the paradigm of PCOS management.

Keywords: PCOS, homeopathy, keynote

P028. Homeopathic Management of Tomato Leaf Curl Virus Using Psorinum

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Background: Tomato leaf curl virus (ToLCV) disease vectored by whitefly Bemisia tabaci, is the most devastating disease of cultivated tomato (Lycopersicon esculentum), causing 38-100% yield loss, depending on the stage of the crop at the time of infection. This has stimulated research to find a suitable remedy. Use of the homeopathic nosode Psorinum in agriculture was to validate the potential of agro-homeopathy in viral infection. According to Dr. Samuel Hahnemann, 'Psorinum is not a simple biotherapy, rather it is a homoeopathic remedy having been the object of experiment, according to the methodology of proving'.

Methods: The study was conducted in Sarada Krishna Homoeopathic Medical College, Kulasekharam, Kanyakumari district, Tamil Nadu, India during the years 2017-18. The study aims at observing variation in Psorinum treated and untreated groups of tomato plants susceptible to ToLCV infection. The observations identified for study were growth parameters and yield attributes such as duration of flowering and fruiting events. Fruit weight, yield/plant etc. were also calculated. Biochemical characters, such as lycopene and ascorbic acid, were inferred by suitable laboratory protocol. All parameters were expressed as mean \pm SE. Disease incidence by ToLCV was observed at regular intervals by the appearance of key symptoms. Real-time PCR methods were used for the quantification of viral load in Psorinum 30 treated sets of tomato plants along with the control.

Results: Significant variation was observed in growth parameters, especially in height of the plant and fruit weight; yield showed 42.6% greater increase than the control group. Biochemical parameters, especially ascorbic acid showed 12.4% greater increase when compared with the control group. Analysis of virus DNA by RT-PCR showed 31.6% greater reduction of viral load when compared to control group. Statistical analysis of treatments revealed significance at

Keywords: Agro-homeopathy, tomato leaf curl virus disease, real-time PCR

P029. Implication for Hydrogen Free Radical Formation in the Presence of Hydrogen Nanobubbles

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Strong vertical shaking in the traditional homeopathic preparation can cause the generation of air nanobubbles in water. Nanoparticle Tracking Analysis (NTA) images of 4CH and 30CH water may reveal Brownian bubbles with a mean diameter of around 100nm and concentration of $3-4 \times 10^7$ particles/mL. Nanobubble research may provide a new approach to understanding of homeopathy as there exists a close parallelism between homeopathic dilution and nanobubble water.

Using NTA, we have studied a puzzling phenomenon of size-dependent spontaneous combustion inside H₂/O₂ nanobubbles in the mixture of hydrogen and oxygen nanobubble water. We measured time-dependent NTA size distributions of H₂/O₂ nanobubbles after mixing H₂ and O₂ nanobubble water to determine the size of the mixed gas nanobubbles pertaining to the combustion. We found an initial increase and subsequent decrease in the total volume of the nanobubbles, showing a significant reduction in the number density of the nanobubbles with less than 100 nm. This implies water formation at room temperature through hydrogen free radical generation that is conjectured from the experiments of hydrogen nanobubble effects found by electron spin resonance and fluorescence spectroscopy and by

Keywords: Hydrogen, nanobubbles, water, hydrogen, free radical generation

P030. Urticaria and Homeopathy: The Unmet Clinical Needs Vinita Pandey¹

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Background: Chronic urticaria (CU) is a disturbing allergic condition of the skin, defined as the occurrence of hives, pruritus and/or angioedema for more than 6 weeks.

Aim: To assess the clinical outcome associated with individualised homeopathic remedies on CU symptoms in patients who had remained symptomatic despite concomitant antihistamine therapy.

Methods: We performed a clinical observational study of ten patients in the treatment of CU symptoms over a twoyear period (2015 and 2016). Informed consent was obtained from each patient. End points were measured from a daily diary that reflected weekly hive score (WHS) and weekly itch score (WIS). QoL was evaluated using a CU quality of life questionnaire (CU-Q2oL) score.

Results: Overall average WHS at baseline was 18.2 (standard deviation, SD, 3.6) and WIS was 21 (SD, 0). At 4 weeks, 8 weeks and 12 weeks the mean (SD) change from baseline in the WHS was -9.7 (4.4), -13.3 (4.8) and -18.2(3.6) respectively. Mean (SD) changes from baseline in WIS after 4 weeks, 8 weeks and 12 weeks were -8.6 (2.4), -15(2.8) and -20.9 (0.3) respectively.

Overall mean CU-Q2oL scores at baseline of all ten patients were 76.0 (1.0) which improved to 43.7 (0.5) at week 4, 28.2 (0.4) at week 8 and 23.9 (0.2) at week 12. In all patients, use of antihistamine decreased from 10 mg twice daily at study baseline to none at week 12.

Conclusion: Individualised homeopathic treatment was associated with alleviation of CU symptoms, enabling reduction in use of conventional treatment. The results presented in this study can be considered as a step towards a pilot pragmatic study using homeopathy.

Keywords: Chronic urticaria, weekly hive score, weekly itch score

P031. Exploring the Tools for Large-Scale Data Collection and Analysis in Clinical Practice in Africa. Developing **Methodologies for Measurement of Patient Outcome**

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The utilization of data collection systems and analysis tools is a key component of health information systems and used to formulate health policy and analyse operational efficiencies and health outcomes. In the quest to find scientific

evidence to validate homeopathy, emphasis on the clinical outcome of homeopathic treatments as part of operational research is a valid and important contribution to homeopathic

Two homeopathy projects have been exploring ways in which evidence from clinical practice can support homeopathy in their countries for ten years. The Swaziland Homeopathy Project (SHP) and the Kenya School for Integrated Medicine (KSIM) have been collaborating in producing clinical evidence and together have over 10,000 cases in their database system.

SHP uses the Access database to evaluate outcomes, using a Visual Analogue Scale (VAS) which is a psychometric response scale that can be used in questionnaires. It also uses a Karnofsky/Lansky Performance Status to evaluate overall functionality. These scoring mechanisms were chosen to evaluate overall wellbeing and individual symptom scores in an African context. KSIM is working on a five-year project sponsored through the European Union with the Ministry of Health, Kenya. It has introduced an innovative data collection system based on DHIS2 (District Health Information System 2), an open-source software platform used by 55 countries worldwide. KSIM has adapted DHIS2 to homeopathy data collection, also using VAS and Karnofsky scores to evaluate homeopathic outcomes. Both data collection approaches (Access and DHIS2) are being evaluated and monitored for their efficiency and usefulness.

Each innovative data collection model has the potential to create a very large database of clinical outcomes in homeopathy. VAS and Karnofsky scores have been shown to be useful tools for evaluating clinical outcomes in an African country. Homeopathic outcomes show positive results, and developing an online data collection system with DHIS2 shows especial potential in clinical situations in Africa and beyond.

Keywords: Evidence, clinical outcomes, information systems

P032. Hypericum perforatum to Improve Post-Operative Pain Outcome After Lumbar Mono-segmental Spinal Microdiscectomy (HYPOS) - Preliminary Results of a **Randomized Controlled Trial**

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Background: Potentized Hypericum perforatum is known as a remedy for lancinating pain when nerval damage is involved. We aimed at investigating whether additional intake of Hypericum C200 might lead to a significant decrease of perceived pain and conventional pain medication compared to placebo in patients undergoing microdiscectomy.

Methods: Between 2015 and 2018 a randomized controlled trial was conducted in the Department of Neurosurgery at the Community Hospital Herdecke. In-patients undergoing spinal microdiscectomy were randomly selected into homeopathic treatment or placebo, both in addition to usual pain management. 3 globuli of either verum or placebo were administered after surgery every 12 hours for 3–5 days. The primary outcome was pain reduction at these 3-5 postoperative days, measured on a visual analogue scale. Statistical analysis was done by means of a repeated measures model.

Results: A total of 95 patients were included in this preliminary analysis, of which 47 patients (49.5%) received homeopathic treatment. No significant between-group difference was found with respect to patient demographics such as gender (Control: 25 (52.1%) versus Verum: 21 (44.7%) male patients; age (mean: 52.5 ± 14.2 versus 52.2 ± 13.5 years); body mass index (mean: 26.8 \pm 4.2 versus 27.9 \pm 5.2 years); and duration of surgery (mean: 62.5 ± 20.6 versus 66.4 ± 28.3 min). With respect to pain reduction, there was a similar decrease in pain intensity from 5.6 \pm 2.3 (Control) and 5.8 \pm 2.6 (Verum) to 3.0 \pm 2.6 (Control) and 3.0 \pm 2.5 (Verum), with no significant group differences based on complete case analysis (N = 66).

Discussion: This preliminary data analysis showed comparable socio-medical parameters between the two groups. The results however did not confirm any difference in pain reduction between them. Further analyses of the intake of pain medication and the evaluation of sensory and affective pain perception are currently underway.

Keywords: Microdiscectomy, Hypericum perforatum, pain, RCT

P033. Systematic Observations Suggest a Non-material Mode of Action in Substances Diluted beyond Inverse Avogadro's Number - A Pre-Pilot Study in Human **Volunteers**

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Background: The mode of action of potentised substances beyond inverse Avogadro's number is yet unknown, despite proven effects on complex biological systems, such as plant and animal laboratory experiments, homeopathic drug provings and therapeutic use in humans.

Objectives: To demonstrate (i) individual susceptibility to homeopathic ultra-high diluted remedies (HUHDRs) and (ii) non-material effects of HUHDRs in humans.

Method: Healthy volunteers participated in an observational application trial of different HUHDRs in various potencies using a gas discharge visualisation (GDV, biowell.com) camera for biometric measurement of changes in the bioelectric field taken from electrophotonic emissions of the fingertips.

Results: In all three participants, without ingesting but holding the respective probes of HUHDRs, (i) individual reactions to certain remedies, (ii) non material-transferred effects, (iii) time-related instant or post-withdrawal vanishing effects, and (iv) individual specific reaction patterns to socalled constitutional remedies were detected, on both the psycho-emotional and the physiological level.

Conclusion: This is the first published systematic approach to demonstrate a non-material field-like mode of action of HUHDRs in humans by GDV. This non-invasive, wellestablished and safe biometric method is a promising step of biomarker development in HUHDR research. Furthermore, these preliminary results might draw attention to this way of demonstrating effects of HUHDRs and encourage further indepth research in this field.

Keywords: Mode of action, ultra-high dilution, biometric method, gas discharge visualization

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P034. Clificol: First Results from Carcinosinum Patient Cases Carlo Maria Rezzani¹

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Background and Aims: Clificol (Clinical File Collection) is an International databank able to store and analyse clinical cases collected from over 20,000 RadarOpus users and from You-Cure.

The homeopaths first collect the data in WinCHIP, which guarantees the completeness and the standardization of the information (thanks to the use of a dedicated pick-list).

The stored data is then validated by WinCHIP and sent to the Clificol databank where it is checked by a qualified staff member to ensure the integrity of all the data.

The data, according to the General Data Protection Regulation (GDPR) rules, is sent in an anonymous way.

Method: We analysed the output of the data (4,659 cases) from different perspectives:

- · Epidemiological: patient age, gender, acute and chronic illness distribution.
- Homeopathic: we studied the pathologies most frequently treated with Carcinosinum and the frequency of the repertorial symptoms.

Results and Conclusion: The author will show the cases studied with the help of technology to obtain high-quality data. The open problems that the homeopathic clinical research involves are described.

Keywords: Clificol, WinCHIP, RadarOpus, You-cure, methodology

P035. A Randomized Controlled Study on Cognitive Effects of Anti-cancer Therapy in Patients with Breast Cancer Treated with Rehabilitation Exercises, Diet and Add-on Homeopathy and Acupuncture/Auriculotherapy Elio Rossi¹, Stefania Tocchini², Marco Picchi¹, Cristina Noberasco¹, Lucia Da Valle²

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Background and Aims: Chemotherapy-related cognitive impairment (CRCI) - 'chemobrain' - includes mental fatigue, and impairment in attention, processing speed and short-term memory.

Aims: This study evaluates the efficacy of complementary integrative medicine (CIM), acupuncture and homeopathy, compared to standard care in relieving CRCI.

Material and Methods: Inclusion criteria: females aged 18 to 70 years, with a primary diagnosis of early breast cancer (stage I-IIIA), treated with adjuvant chemotherapy regimens and/or endocrine therapy; written informed consent; educational level sufficient to understand the neurocognitive tests. Stratification: menopausal status; chemotherapy regimens; endocrine therapy.

Treatment: Acupuncture: basic acupuncture formulas Baihui (GB20), ExYintang1, Taixi (KI3). Sessions will be scheduled once a week for 4 weeks, followed by one month of auriculotherapy; at the end another 4 weekly sessions of acupuncture. Homeopathy: a magistral preparation including Helleborus niger 15 CH, Plumbum metallicum 6 CH, Phosphorus 15 CH, Cerebral cortex 5 CH and Nerves 5 CH, three granules three times a day for 3 months.

All the patients will receive dietary advice to reduce body inflammatory state and at the end of chemotherapy they will undergo a neuropsychological visit performed by a psychologist properly trained for cognitive function assessment. During the study, blood samples for plasma/serum

analysis of BDNF (brain-derived neurotrophic factor), IL-6 and TNF (at baseline and 12 months) will also be collected.

The number of patients recruited will be 300, divided in three groups: 1) 100 with rehabilitation exercises and dietary advice, plus homeopathy; 2) 100 with rehabilitation exercises and dietary advice, plus acupuncture and auriculotherapy; 3) 100 with rehabilitation exercises and dietary advice as control group.

Results: The study is currently in its early stages, so there are no results at the time of writing. We expect to present the first preliminary results during HRI Congress.

Keywords: Breast cancer patients, anticancer therapy, cognitive impairments, homeopathy, complementary medicine

P036. A Quantitative Analysis on Effectiveness of Homeopathic Treatment in the Management of Allergic **Rhinitis in Children**

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Background: Allergic rhinitis affects about 10-40% people globally. About three-fourths of Indian children suffering from allergic rhinitis are found to be symptomatic, hampering quality of life and emerging as a leading cause of school absenteeism. Homeopathy aims to boost immunity, alter susceptibility and decrease the predisposition towards allergies.

Aim: To determine the role of homeopathy in treating allergic rhinitis - reducing the frequency and intensity of attacks, boosting immunity and increasing tolerance towards various allergens.

Methods:

- A descriptive, observational study, including 30 cases.
- An evaluation tool, ARIA (Allergic Rhinitis & its Impact on Asthma), was used to stage the allergic rhinitis before and after treatment, and paired t-test was applied.
- During homeopathic treatment a 2-fold approach was used - a medicine to boost immunity and modify the allergic tendency during symptom-free periods, and an acute remedy during exacerbation of the allergic episode.
- Outcome measurement was done based on the posttreatment stage. Symptoms persisting in stage 1 and 2 were considered as improvement, and symptoms ≤ 4 days a week or \leq 4 weeks were considered as stage 0 or cured.

Results: Analysis of the cases after 6 months of treatment revealed that 70% of included cases were cured, 27% showed improvement at 3% were drop-outs.

Conclusion:

- Based on the results, the null hypothesis was rejected and it was concluded that homeopathy is effective in treating paediatric allergic rhinitis by modifying the allergic
- The objective of reducing the frequency and intensity of episodes after treatment with homeopathy was attained, as evident from the post-treatment analysis.
- Allergen tolerance towards weather change and coloured food was achieved.

Keywords: Allergic rhinitis, homeopathy, immunity, susceptibility

P037. Systematic Review of Conceptual Criticism of Homeopathy

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Background: Homeopathy, with its long tradition as complementary medicine therapy, is often a subject of debate, especially in non-peer-reviewed media, in which its effects and plausibility are highly discussed. Due to the lack of knowledge on a remedy-specific mode of action, pre-clinical and clinical effects of homeopathy are questioned, and lack of scientific evidence emphasized. This systematic review aims to summarize and evaluate peer-reviewed scientific articles regarding conceptual criticism of homeopathy.

Methods: The literature search strategy included original peer-reviewed scientific articles on conceptual criticism of homeopathy, following the current recommendations of PRISMA (Preferred Reporting Items for Systematic reviews and Meta-analysis Approach). The databases Cochrane Library, EMBASE, Europe PMC, PhilPapers, PubMed and Web of Science provided the basis of the literature search. Editorials, comments, reviews, meta-analyses, clinical trials and experimental studies were not considered.

Results and Conclusion: Only a few articles were found. Implausibility of homeopathic basic principles (law of similars, potentization procedure) according to the current state of scientific knowledge is one of the statements made. In some cases, further conclusions are drawn, such as that homeopathy is ethically unacceptable. Based on the present analysis of the scientific peer-reviewed literature, the current discussion in the public media is not mirrored by a corresponding scientific debate.

Keywords: Homeopathy, conceptual criticism, scientific evidence

P038. Integration of Homeopathy in Indian Healthcare Deepti Singh Chalia¹, Harleen Kaur¹, Raj K. Manchanda¹ ¹Central Council for Research in Homoeopathy, New Delhi, India

Background (Why to Integrate): WHO endorses health service delivery to become more integrated and peoplecentric by re-orienting the model of care and coordinating services within and across sectors. It is thus essential to integrate homeopathy in national health programs of countries that can aid in reducing healthcare burden and diminish costs. India's current healthcare system is not sustainable for its population. With rapid health transition, India is facing a 'triple burden of disease' in the form of unfinished cases of communicable diseases, rising non-communicable diseases that are related to lifestyle, and the emerging threat of infectious diseases. On other hand, there is lack of sufficiently trained healthcare manpower.

Method (How to Integrate): Homeopathy is playing a considerable role in meeting the health care needs of the population in India by its integration at appropriate levels, within specified areas of responsibility and functioning, in the overall healthcare delivery system, especially with regard to the preventive, promotive and public health objectives. The Government of India has launched several schemes and national programs wherein homeopathy is being utilized for its inherent advantages of its patient-centric approach, cost-effectiveness, ease of administration and gentle action.

Result and Discussion (Current Integrated Scenario in India): The results of a nationally representative health

survey, 2014, reveals that homeopathy has significant presence in India, with popularity more among children (<5 years), particularly in urban areas. Homeopathy is widely practiced in Uttar Pradesh, Kerala, West Bengal, Orissa, Andhra Pradesh, Maharashtra, Punjab, Tamil Nadu, Bihar, Gujarat and the north-eastern states of India. India has a very conducive infrastructure, with 284,471 homeopathy doctors, 201 under-graduate and 50 post-graduation colleges, 7,544 government-run clinics and 164 hospitals pertaining to homeopathy that are run by state governments and municipal bodies - all of which exists as a sustainable support to public health. The growth rate of homeopathy has increased from 1,935 doctors per 10 million population in 2007 to 2,136 doctors per 10 million population in the year 2017.

Through the Indian model of meaningful integration of homeopathy in healthcare, we are focusing on providing education through the university system, adequate drug control measures, high quality research and participating in public health initiatives. The resulting improvement in health outcomes of the country thereby contributes towards achieving Universal Health Coverage.

Keywords: Homeopathy, integrated health service, national health profile, universal health coverage

P039. Medicinal and Placebo Effects of Homeopathic **Remedies: A Comparative Study of Patients with** Somatoform Low Back Pain and Patients with Pathological Low Back Pain

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Introduction: Low back pain is the most common musculoskeletal disorder reported in clinical practice. Chronic low back pain is also a leading symptom of somatoform pain disorder, where the physical symptoms often are not physically explainable. The study was intended to find whether there was any difference in the effect of individualized homeopathic medicines, compared with individualized homeopathic medicines when given along with placebo, compared with placebo alone, in pain and functional disability, anxiety, depression and wellbeing in patients with pathological low back pain and in patients with somatoform low back pain.

Methods: A pre-post experimental design was used for the study, with pain as the primary outcome variable and anxiety, depression and wellbeing as the secondary outcome variables based on the Oswestry low back pain scale, the Hamilton Anxiety Rating Scale, the Beck Depression Inventory and the PGI General Wellbeing Measure. 225 patients with pathological low back pain and 225 patients with somatoform low back pain were each divided into three separate categories, receiving either homeopathic medicine alone or homeopathic medicine with placebo or placebo alone. Institutional ethical committee clearance was obtained, and patients were enrolled only after giving their informed consent. Data were analysed using ANCOVA.

Conclusions: Major findings showed that homeopathic medicine when used alone can be more effective in managing pain and other co-morbid conditions in patients with low back pain of a pathological nature. Homeopathic medicine in combination with placebo had an effect in some cases. Placebo alone was found to be mostly ineffective on pain and disability, anxiety and depression, but was effective on the wellbeing of patients with somatoform low back pain.

Keywords: Homeopathy, placebo, low back pain

P040. A Time-to-Deterioration (TTD) N-of-1 Clinical Trial Design for Use in Homeopathy Research

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Background: Application of the randomised controlled trial (RCT) in research into individualized homeopathy has several known limitations, such as selecting the appropriate individual remedy, and inherent ethical problems of placebo interventions.

Methods: Based on recent considerations of the possible use of N-of-1 trials in homeopathy and its limitations, we developed a modification of the N-of-1 trial design.

Results: The key element of the proposed study design is to select 'time to deterioration' (TTD) after intervention as primary outcome in an N-of-1 trial. We assume a positive homeopathic treatment effect relative to baseline on a given measurement scale (e.g. Conners Global Index (CGI) in ADHD). If treatment consists e.g. of a few doses of Q-potencies, deterioration can be expected after some time. After reaching a particular threshold value (TV) in the outcome scale (e.g. 30% decrease of CGI), the next trial medication is given. Verum and placebo are administered double-blind and randomly in time. Assuming that verum has stronger effects than placebo, the timespan until TV is reached is longer after verum application compared to placebo. The adequate homeopathic remedy can be determined in an open or singleblind screening phase with an adequate success criterion (e.g. 50% improvement in CGI). Data from TTD N-of-1 trials can be easily aggregated and synthesized in meta-analysis, since the outcome is always measured in time units.

Discussion: The TTD trial design is appropriate for chronic stable conditions. Major advantages are: placebo phases are self-limiting and as short as possible, thus minimising ethical problems and patient drop-out; carry-over effects are limited by the choice of the threshold value; TTD data yield information on duration and time-course of homeopathic as well as placebo treatments. Placebo could be replaced by another homeopathic remedy to compare efficacy of different treatment options.

Keywords: N-of-1 trial, research methodology, homeopathy

P041. Ultradiluted *Viscum album* in the Treatment of **Melanoma in a Dog (***Canis familiaris***) – Case Report** Ana Catarina Valle^{1,2}, Rosangela Andrade^{1,4}, Marcelo Sibata^{3,4}, Aloisio Carvalho⁵

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Introduction: Melanoma is the sixth most common leading cancer worldwide and its incidence is continuously rising. The management of patients with melanoma has been historically challenging, with extremely low survival rate. Thus, the emergence of innovative treatments becomes a necessity. Homeopathy, introduced by Hahnemann, becomes an interesting treatment option, especially taking into account the levels of similarity. Ultradiluted Viscum album (mistletoe) has been used, based on the anatomic-pathological similitude model for cancer control. The aim of this work

involves the treatment of melanoma in a dog, through peritumoral subcutaneous applications of ultradiluted mistletoe.

Material and Methods: A 10-year-old male non-pedigree dog, weighing 22 kg, attended the NaturalPet Vet Clinic, in Brasilia, Brazil, in August 2018. Physical examination showed a black skin wound, 2 cm in diameter, in the medial face of the scapula, present for 2 days. Material for biopsy was collected. The patient was medicated with *V. album* D3, peritumoral subcutaneously, every 7 days for 4 weeks. After that time the animal was medicated with *V. album* D3, D6, D9, D12, D30 in combination, 3 times per week.

Results: The biopsy revealed melanocytic melanoma. A reduction of the wound was observed at the end of 4 weeks. The patient was periodically assisted and returned to the veterinarian's office once a month for a follow-up analysis. At the time of writing, after 6 months of treatment, the animal remains unchanged and in perfect health.

Conclusion: V. album proved to be an important therapeutic tool for the treatment of canine melanocytic melanoma: the therapy significantly reduced the wound manifestation of the disease, with no side effects such as leucopenia. Throughout the treatment period the patient remained without physical, hematological and biochemical alterations. The patient's overall health was preserved, and the quality of life was improved, with no alterations similar to the original lesion. However, further studies are needed to fully understand how homeopathic medicines act in the treatment of this disease.

Keywords: Mistletoe, cancer, homeopathy

P042. Mixed Methods Homeopathy Research of the '3 Hs': History; Health-Related Quality of Life; Hearing the Voices of Parents

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Background: Homeopathy is a charismatic medical practice but an under-investigated clinical field. We present a research contribution from Bulgaria. The aim is three-fold, within the '3Hs' framework: 1) to review the History of homeopathy in a post-communist country; 2) to investigate the Health-related Quality of Life (HrQoL) of chronically ill homeopathy patients; and 3) to Hear parents' voices.

Methods: The observational multi-centered study (Ethical approval, 2016) followed a mixed methods convergent-parallel design. The EQ-5D-3L instrument was used during the quantitative phase for assessing HrQoL of patients receiving individualized homeopathic medical treatment (IHMT) for more than a year (n=211; >18 years old); there were no restrictions on the consultation length and prescribed homeopathic remedies. The qualitative phases included historical research and in-depth interviews with parents who choose homeopathy for their children (n=19). The research settings were out-patient homeopathic clinics.

Results:

- 1. Homeopathy was introduced into Bulgaria by Dr Mirkovic in 1885; its use was forbidden in 1944. Its modern history began in 1992 with the first teaching course; legal recognition was granted in 2001.
- 2. HrQoL results: patients without problems in any of the five domains of EQ-5D represented 29.5% of the total (n=65); only 6.2% (n=13) reported any extreme problem. The mean state of health/VAS was 75.3 (SD, 18.2). More than half of the patients (n=137, 64%) had used IHMT for

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longer than 3 years. There was a positive correlation between duration of IHMT and VAS-self-rated valuation (r = 0.171; p = 0.013). More than a quarter of the patients (n = 64, 30.3%) were using homeopathic remedies as complementary to conventional (n = 39, 18.5%) or to non-conventional therapies (n = 25, 11.8%). Further research is needed to prove causality of the intervention.

3. Hearing parents' voices was considered in four fields: Choice of homeopathy; Family dynamics; Supportive environment; Relationships (parent-child-homeopath).

Conclusion: The presented research promotes integration of homeopathy in the national healthcare of Bulgaria. Keywords: Homeopathy research, history, EQ-5D-3L, Bulgaria

P043. Developing Homeopathic Treatment Guidelines for Patients with Hepatitis C

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Hepatitis C has been studied for a long time. Despite consensus that, overall, reduction in inflammatory activity prevents progression to fibrosis and increased mortality, that same reduction usually prevents progression to cirrhosis and hepatocellular carcinoma thus improving the quality of life of patients. In the Hepatology Service of the Hospital Universitário Antonio Pedro, linked to the Faculty of Medicine of the Universidade Federal Fluminense (UFF), many patients, even though they are regularly followed, are unable to follow the recommendations of conventional treatment - due to medication side effects or because they have achieved cure criteria at the end of therapy. Faced with this demand, we assume the challenge of designing homeopathic treatment guidelines for hepatitis C, based on the assumptions of this integrative practice and guided by Carillo's Theory of Complex Systems. The project initially involved the participation of 42 patients. As a result, we studied the materia medica of Zincum metallicum and China officinalis for liver support, given their tropism for the liver, initiating one or another (or combining

Of the 42 initial patients, 4 withdrew from the protocol for personal reasons, leaving 38 participants. In the first consultation we prescribed the liver support remedies. In addition, we proceeded with semi-structured interviews, asking the patients about the most significant changes they were experiencing in their quality of life. Patients' selfreported major symptoms were determined using the validated Likert-scale questionnaire, WHO-QOL 100 (World Health Organization-Evaluation of Quality of Life). After 14 months of homeopathic treatment, there was significant improvement in all symptoms reported by patients, in the order of 75%, demonstrating that homeopathy is a feasible adjunctive therapy, particularly addressing improvement in quality of life. Further studies are indicated.

Keywords: Homeopathy, hepatitis C, liver, welfare

P044. Constitutional Homeopathic Treatment in Cases of Pre-diabetes and Insulin Resistance at a Primary Health **Centre: A Feasibility Study**

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Background: India, a recognized epicentre of the global diabetes mellitus pandemic, is witnessing an increasing number of people being diagnosed with pre-diabetes and insulin resistance. Having pre-diabetes initiates the longterm damage of diabetes, and without intervention it is likely to become type 2 diabetes in 10 years or less.

Aim: To assess the feasibility of constitutional homeopathic treatment along with therapeutic lifestyle changes in cases of pre-diabetes and insulin resistance.

Methods: Between 1st April 2014 and 29th July 2016, all patients who were diagnosed either with pre-diabetes [ICD10: R73.09; abnormal fasting blood glucose level (100-125 mg/dl), an elevated HbA1c level (between 5.7 and 6.4%), or an abnormal glucose tolerance test (140-199 mg/dl)] or with insulin resistance [ICD10: E88.81] at the World University Services Health Centre, South Campus, Delhi University (Primary Health Centre), were referred to the co-located Delhi Government Homeopathic Dispensary and enrolled after obtaining due consent. These registered patients were treated with constitutional homeopathic medicines along with therapeutic lifestyle changes and followed up every 4–6 weeks. They were not on any supplements or hormonal medications during the course of observation.

Results: Out of the 32 registered cases, results were analysed clinically and serologically in 25 [12 females and 13 males; aged 14 to 67 years] at 6-monthly intervals, based on the pre-defined inclusion criteria. 22 different remedies were prescribed in these cases, after individualization, in centesimal potencies. Only one person required the same remedy in LM potency due to failure of response to the centesimal. Serological markers normalized under homeopathic treatment in 88% of cases.

Conclusion: The results of the study suggest the feasibility of constitutional homeopathic treatment in cases of pre-diabetes and insulin resistance. However, a pragmatic comparative study would more effectively evaluate the role of homeopathic treatment in these clinical conditions.

Keywords: Pre-diabetes, insulin resistance, homeopathy

P045. An Open-Label Pilot Study to Explore Usefulness of Homeopathic Treatment in Scabies in a Primary Health **Centre Catering to a Low Socioeconomic Populace**

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Background and Aim: Scabies affects around 200 million people at any one time, causes an intensely itchy rash, and may lead to secondary bacterial infection, autoimmune disease and poor QOL (quality of life). The WHO recommends that scabies be added to the neglected tropical disease portfolio and calls for action to improve control efforts. There are a number of medicines cited in homeopathic literature which can be used for treatment of scabious infestation. A pilot study was therefore undertaken to explore the usefulness of homeopathic medicines in the treatment of scabies.

Methods: In this study, more than 5,000 patients were screened at Delhi Government Homeopathic Dispensary Aali Village (DGHDAV), New Delhi, India between 1st April 2014 and 31st March 2015, and 146 were enrolled on the basis of pre-defined inclusion criteria. A single homeopathic medicine was prescribed for each patient with the help of materia medica and/or repertory on the basis of presenting symptoms. Response to homeopathic treatment was assessed on VAS (visual analogue scale) for itching and ORIDL (Outcome in Relation to Impact on Daily Living) scores for QOL.

Results: Remedial response was gauged in most of the patients within 48 hours and complete recovery was seen in 79.5% cases in a mean time of about 22 days. Significant differences were recorded in patients in their pre- and post-treatment VAS and ORIDL scores.

Conclusion: Homeopathic medicines have potential to treat scabious infestation by removing pruritus, eradicating lesions, restoring sleep and improving QOL. Homeopathy may provide a cost-effective treatment for scabies and a randomized controlled trial should be considered.

Keywords: Scabies, homeopathy, pilot study

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