



**CUTTING EDGE
RESEARCH**
IN HOMEOPATHY

ROME 2015

2ND HRI International Homeopathy Research Conference



**Cutting Edge Research
in Homeopathy**

5-7 June 2015
Radisson Blu Hotel
Via Filippo Turati, Rome, Italy

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Welcome

We would like to welcome you to the Homeopathy Research Institute's 2nd International Homeopathy Research Conference, continuing our ongoing theme of '**Cutting Edge Research in Homeopathy**'.

In the two years since HRI's inaugural conference in Barcelona (www.HRIBarcelona2013.org), interest in homeopathy research has continued to grow dramatically, both within the homeopathic profession and externally. This reflects the crucial role rigorous research is now playing in the development of homeopathy.

HRI conferences provide a unique experience within the worldwide conference calendar – a two and a half day international event dedicated solely to homeopathy research, providing a forum for the sharing of ideas and the creation of international scientific collaborations.

HRI is proud to have brought together high calibre speakers from 14 countries to deliver a diverse programme, giving attendees a snapshot of the latest developments across various sub-fields of homeopathy research, including:

- Clinical research: quantitative and qualitative
- In vitro research
- Fundamental research
- Pathogenetic trials (provings)
- Safety and Ethics

The 'HRI Rome 2015' has been organised by our Conference Organising Committee, with additional input from the Conference Advisory Committee and HRI's Scientific Advisory Committee. We are delighted to be holding this event in the fabulous city of Rome and would like to thank the Italian homeopathic community for their invaluable support in preparing for this event.

It only remains to invite you to join us in making the most of this opportunity to share scientific knowledge and form closer links with colleagues from around the world.

Alexander Tournier & Rachel Roberts

HRI Management Team

Conference organising committee

Rachel Roberts (Chair) – *HRI Chief Executive*

Simon Wilkinson-Blake – *HRI Company Secretary & Event Organiser*

Dr Alexander Tournier – *HRI Executive Director*

Alastair Gray – *HRI Advisor on Communications & Homeopathic Pathogenetic Trials*

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Conference advisory committee

Dr Peter Fisher – *Director of Research, Royal London Hospital for Integrated Medicine, UK*

Stephen Gordon – *General Secretary, European Central Council of Homeopaths, UK*

Dr Thomas Peinbauer – *President, European Committee on Homeopathy, Austria*

Dr Elio Rossi – *Director of Homeopathic Clinic, Provincial Hospital of Lucca, Italy*

HRI Rome 2015 – Key facts

- 116 abstracts submitted
- 38 oral presentations, 7 poster talks and 34 poster presentations from researchers in 21 countries
- Over 250 delegates attending, representing more than 30 countries

About HRI

The Homeopathy Research Institute (HRI) is an innovative charity, created to address the need for high quality scientific evidence in homeopathy. We use our resources and expertise to foster new projects and to improve the quality of research being carried out in the field.

HRI is dedicated to the evaluation of homeopathy using the most rigorous scientific methods available and communicating the results of such work beyond the usual academic circles.

As well as providing academic support to several projects around the world, we are currently funding seven active research projects. These range from pragmatic randomised controlled trials assessing homeopathy for the treatment of ADHD and depression to investigating the mechanism of action of homeopathic medicines.

The Institute's day-to-day operations and management are the responsibility of Rachel Roberts (Chief Executive) and Alexander Tournier (Executive Director), guided by our Board of Trustees. The HRI Scientific Advisory Committee (SAC), a team of independent world experts in homeopathy or CAM research, provide the strong scientific foundations essential to our work.

For more information visit www.HRI-research.org.



HRI Management Team



Dr Alexander Tournier
BScCantab PhD LCHE RSHom
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Rachel Roberts
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Dr Alexander Tournier BScCantab PhD LCHE RSHom
HRI Executive Director and Independent researcher, France

Programme

Pre-conference events

THURSDAY 4th JUNE 2015

- 14:00 – 17:00** **Workshop: ‘Harmonised proving guidelines of ECH & LMHI’** – Radisson Blu Hotel
- 18:00 – 20:00** **Conference Registration** – Radisson Blu Hotel
- 18.30 – 20.00** **Welcome drinks** – **Stadio di Domiziano, Piazza Navona**

Day 1 – Cutting Edge Research in Homeopathy

FRIDAY 5th JUNE 2015

- 08.00** **Conference Registration** – Radisson Blu Hotel
- Plenary Sessions – full day**
- 09:00 – 09:30** **Opening Ceremony**
- 09:30 – 10:30** **Homeopathy Research – the State of Play and the Way Forward**
Chair: Dr Alexander Tournier
- 09.30** **Prof Paolo Bellavite**, Italy. *Basic research on homeopathic principles*
- 10.00** **Dr Klaus von Ammon**, Switzerland. *Contribution of clinical observations to the discovery of mode of action of homeopathic medicines*
- 10:30 – 11:00** Coffee
- 11:00 – 12:20** **Clinical Research 1**
Chair: Dr Elio Rossi
- 11.00** **Dr Sadanandan Gopinadhan**, India. *Homeopathic management of Attention Deficit Hyperactivity Disorder: A randomized placebo controlled pilot trial*
- 11.20** **Petter Viksveen**, UK. *Homeopathy in self-reported depression: A pragmatic randomised controlled trial*
- 11.40** **Dr Martien Brands**, Netherlands. *A comparative study on the treatment of malaria using complex immunotherapy and Coartem in homeopathic clinics in Kenya– A randomized controlled trial*
- 12.00** **David Brulé**, Canada. *Feasibility and clinical results of a pilot trial of individualized homeopathic treatment of fatigue in children receiving chemo therapy*
- 12:30 – 14:00** Buffet Lunch

- 14:00 – 15:20** **Safety & Clinical Research**
Chair: Dr Petra Klement
- 14.00 **Rachel Roberts**, UK. *How safe is homeopathy? An analysis of the Posadzki et al. 2012 safety paper and fresh review of the same literature*
- 14.20 **Dr Peter Fisher**, UK. *Homeopathy and public health: Multimorbidity, polypharmacy, antimicrobial resistance, adverse drug reactions and homeopathy*
- 14.40 **Prof Jennifer Jacobs**, USA. *Homeopathic treatment of respiratory illnesses in children: Results from two randomized trials*
- 15:20 – 15:50 Coffee
- 15:50 – 16:50** **Poster Talks**
Chair: Dr Peter Fisher
- 15.50 **Dr Kimberlee Blyden-Taylor**, Canada. *Effectiveness of the concomitant use of psychotropic pharmaceuticals and individualized homeopathic treatment: A Delphi study*
- 16.00 **Philippa Fibert**, UK. *A protocol for a randomised controlled trial of the effectiveness of treatment by homeopaths for ADHD*
- 16.10 **Dr Lefteris Tapakis**, Greece. *Statistical analysis of 156 cases of depression treated with classical homeopathy*
- 16.20 **Christa Raak**, Germany. *Hypericum perforatum to improve pain outcome after monosegmental spinal stenosis surgery – Study protocol*
- 16.30 **Alison Fixsen**, UK. *Homeopathic treatment for otitis media in children: the case for pragmatic trials*
- 16.40 **Dr Helene Renoux**, France. *Common points, peculiarities and complementarity of two homeopathic provings methodologies: trituration proving versus long term Hahnemannian proving*
- 16.50 **Dr Silvio Leite Monteiro da Silva**, Brazil. *Neuro-immuno-endocrine modulation in a perinatal model: cytokine production in mice treated by Zincum metallicum*
- 17:00 – 19:00** **Poster Session & Drinks**
- 19:30** **Dinner – Ristorante Acchiappafantasmì**

Plenary Sessions – morning

09:10 – 10:30

Lab-based Research & Mechanism of Action**Chair: Dr Stephan Baumgartner**

09.10

Dr Christian Enderl, Austria. *Repetitions of fundamental research models for homeopathically prepared dilutions beyond 10⁻²³: a bibliometric study*

09.30

Dr Alexander Tournier, France. *Physicochemical investigations of homeopathic potencies: a systematic review of the literature*

09.50

Dr Steven Cartwright, UK. *Solvatochromic dyes detect the presence of homeopathic potencies*

10.10

HRI, GIRI, WissHom. *News from International Homeopathy Research Organisations*

10:30 – 11.00

Coffee

11:00 – 12:20

Clinical Research 2**Chair: Dr Martien Brands**

11.00

Dr Elio Rossi, Italy. *Homeopathy and complementary medicine for cancer patients: results of a survey on integrative oncology centres in Europe*

11.20

Dr Francesca Talarico, Italy. *Single-blind study assessing the individualized homeopathic treatment of cancer patients versus placebo*

11.40

Petra Klement, Germany. *Results of an international, randomised, controlled clinical trial with a complex homeopathic medication in feverish upper respiratory tract infections*

12.00

Dr Miek Jong, Netherlands. *A randomised open comparative clinical trial on the effectiveness, safety and tolerability of a homeopathic medicinal product for frequent acute upper respiratory tract infections in children*

12:30 – 14:00

Buffet Lunch

Parallel Sessions – afternoon

14:00 – 15:20

Lab-based Research (Room L)**Chair: Dr Debora Oliosio**

14.00

Prof Dra Silvana Marques de Araújo, Brazil. *Exploring the model of murine infection by Trypanosoma cruzi to investigate treatment with highly diluted drugs: the influence of Lycopodium clavatum or Phosphorus in Wistar rats*

14.40

Dr Thayna Neves Cardoso, Brazil. *Carbo animalis and immune response to Ehrlich ascites tumor in mice: an experimental model*

15.00

Dr Ganesh Lakshmanan, India. *Effect of ultra-high dilutions of Lycopodium clavatum on reproductive and sexual functions in aged male wistar albino rats*

- 14:00 – 15:20** **Provings (Room M)**
Chair: Dr Helene Renoux
- 14.00 **Prof Ashley Ross**, South Africa. *The translation of prover journals to standard homeopathic formats: accountability and traceability of proving data*
- 14.20 **Dr Peter Smith**, Germany. *A group of recent provings in which the new HPCUS Provings Guidelines were applied: comments on the methodology*
- 14.40 **Alastair Gray**, Australia. *Proving Ethics: At the coalface*
- 15.00 **Dr Jean Duckworth**, UK. *The role of the research ethics committee in providing ethical approval for provings. The findings from a pilot study*
- 15:20 – 15:50 Coffee
- 15:50 – 17:10** **Fundamental Research (Room L)**
Chair: Dr Christian Endler
- 15.50 **Prof Lucietta Betti** (represented by **Dr Giovanni Dinelli**), Italy. *Different approaches in homeopathic basic research: plant-based bioassays and evaporation-induced crystallization*
- 16.30 **Dr Stephan Baumgartner**, Switzerland. *Spatial allocation effects in a potentization basic research model – evidence for field-like effects of homeopathic preparations?*
- 16.50 **Paul Doesburg**, Netherlands. *Replication of specific effects of a Stannum metallicum 30x preparation in a cress seedling/ biocrystallization test system*
- 15:50 – 17:10** **Provings, Methods & Clinical (Room M)**
Chair: Prof Ashley Ross
- 15.50 **Dr Jean Pierre Jansen**, Netherlands. *Homeopathic Pathogenetic Trials (provings) do not always match homeopathic clinical practice. Possible answers from the qualitative research tradition*
- 16.10 **Dr Lex Rutten**, Netherlands. *Improving cough treatment with a mixed methods approach*
- 16.30 **Dr Pawan Pareek**, India. *Homeopathy in iatrogenic disorders*
- 16.50 **Prof Dr Thomas Ostermann**, Germany. *Investigation of effects of highly diluted substances in periodontal inflammation using flow cytometry analysis – a pilot study*
- 20:00** **Gala Dinner – Radisson Blu Hotel**

Plenary Sessions – morning

- 09:10 – 10:30** **Lab-based Research & Clinical Research**
Chair: Dr Miek Jong
- 09.10 **Dr Debora Olioso**, Italy. *Effects of homeopathic Arnica montana on gene expression of human macrophages-results of quantitative real-time PCR*
- 09.30 **Dr Anna Camps**, Spain. *Microimmunotherapeutic administration of cytokines improve the clinical symptoms in EAE, an animal model of Multiple Sclerosis*
- 09.50 **Dr Gustavo Aguilar-Velazquez**, Mexico. *Evaluation of cytotoxic and apoptotic effects of several homeopathic dilutions of Echinacea angustifolia on human breast, cervical and prostate cancer cells*
- 10.10 **Teh Chye Phing**, Malaysia. *A retrospective cohort study on the efficacy of homeopathy compared to homeopathy plus conventional medicine in the treatment of hypertension*
- 10:30-11:00 Coffee
- 11:00 – 12:20** **Clinical Research 3**
Chair: Prof Jennifer Jacobs
- 11.00 **Dr Rajesh Shah**, India. *Clinical trial for evaluation of a HIV Nosode in the treatment of Human Immunodeficiency Virus (HIV) infected participants*
- 11.20 **Dr Rosaria Ferreri**, Italy. *The clinical experience in the centre of integrated medicine - Pitigliano hospital*
- 11.40 **Dr Robert Mathie**, UK. *Systematic review and meta-analysis of randomised, placebo-controlled, trials of individualised homeopathic treatment*
- 12:20 – 12:30** **Closing ceremony**
- 12.30 – 14.00 Optional buffet lunch

Keynote Speakers



Dr Klaus von Ammon

Senior Medical Officer for research in homeopathy, Institute of Complementary Medicine KIKOM, University of Bern, Switzerland

Dr von Ammon completed his medical studies in Hamburg, Marburg/Lahn and Munich, Germany. He trained in neurosurgery in Munich.

Dr von Ammon pursued further studies in Classical Homeopathy in Zurich. He has been Senior Medical Officer in charge of research in homeopathy at the Institute of Complementary Medicine IKOM, University of Bern, since 2001. He has run a medical practice integrating homeopathy in Stäfa near Zurich since 2002. Dr von Ammon has lectured at various homeopathic schools and international congresses since 2005. His main research topics in homeopathy are epidemiology (Swiss-PEK and CAMbrella) and ADHD in children.



Prof Dr Paolo Bellavite

Professor of General Pathology, School of Medicine, Verona University, Italy

Prof Bellavite graduated from Trieste University in 1976, as a medical doctor specialising in Clinical and Laboratory Haematology. He is Professor of General Pathology in the School of Medicine, Verona University. He also holds a course in “Introduction to the knowledge of Complementary Medicines” for graduate students in medicine at Verona University. His research group is focused on molecular and cellular aspects of inflammation, with particular regard to the structure, biochemistry and function of granulocytes (neutrophils and basophils), macrophages and platelets. Prof Bellavite has carried out scientific research in the context of complementary therapeutic approaches, and in particular of high dilutions of agonists and medicines, on cellular and murine models. He has published over 250 scientific papers.



Prof Dr Giovanni Dinelli (representing Prof Lucietta Betti)

Professor, Department of Agricultural Sciences, University of Bologna, Italy

Since 1989, Dr Dinelli has conducted basic and applied research at the Department of Agricultural Science, University of Bologna, Italy. One of the main research items concerns the study of the relationships among agro-techniques (with particular emphasis on organic farming), environmental factors and the expression of nutritional and functional compounds in main crops. Since 2006, he has collaborated with Prof Lucietta Betti (University of Bologna) in the investigation of the role and mechanism of action of ultra-diluted substances in agro-homeopathy at molecular, cellular and whole-plant level. Dr Dinelli has published 180 scientific papers in journals (85 in international journals with impact factor), monographies and proceedings.



Prof Dr Silvana Marques de Araújo

Associate Professor, Universidade Estadual de Maringá, State of Paraná, Brazil

Prof Marques de Araújo graduated in Pharmacy and Biochemistry in 1979. She obtained her MHD (1985) and PhD degree (1994) in Parasitology. She is an Associate Professor at the Universidade Estadual de Maringá, Paraná-Brazil. She participates in two post-graduate programmes. She has experience in parasitology, investigating improved care for patients with positive serology for Chagas disease and toxoplasmosis and alternative approaches (ultra-diluted medicines and physical exercise) to the treatment of experimental infection by *Trypanosoma cruzi* and *Toxoplasma gondii*.



Dr Robert Mathie

Research Development Adviser, British Homeopathic Association (BHA), Luton, UK

During 25 years in the university sector, Robert published approximately 100 peer-reviewed papers, review articles and book chapters. In his current position at the British Homeopathic Association, Robert has been encouraging and assisting homeopathic practitioners to improve the quantity and the quality of their research output. He has developed collaborations with university researchers and has led clinical data collection projects with the Faculty of Homeopathy's doctors, dentists and vets. Publications in homeopathy have been achieved, to date, in 30 peer-reviewed papers and reviews. Since 2010, in a key initiative to identify robust evidence in homeopathy, Robert has extended his work in reviewing and clarifying the research literature by means of a major programme of systematic reviews of randomised controlled trials.



Prof Dr Jennifer Jacobs

Clinical Assistant Professor, University of Washington, USA

Dr Jacobs is a family practice physician specializing in homeopathic medicine. She is also a clinical assistant professor in epidemiology at the University of Washington School of Public Health and Community Medicine. She received her MD degree from Wayne State University and a Masters in Public Health at the University of Washington. She is a former President of the American Institute of Homeopathy, co-founded the special interest group of the American Public Health Association on Complementary and Alternative Health Practices and served on the advisory board of the NIH Office of Alternative Medicine. In addition, she has published numerous homeopathic research studies in peer-reviewed medical journals. Now retired from medical practice, Dr Jacobs continues to consult on homeopathic clinical research.

Pre-Conference Workshop

Harmonising proving guidelines

Thursday 4 June, 14.00-17.00

There is an increasing need for guidelines for homeopathic pathogenetic trials (HPTs) that can facilitate the work of proving coordinators and other stakeholders in this field.

In July 2014, Liga Medicorum Homoeopathica Internationalis (LMHI) and the European Committee for Homeopathy (ECH) decided to harmonise their respective guidelines for provings as a first step towards establishing a best practice document that serves as a basis for further development. Critical comments, suggestions and other feedback on these guidelines are being collected and will inform the revised edition of the guidelines to be published in 2016.

The workshop will present and discuss the guidelines, especially the main issues around which different opinions exist: duration of proving, placebo control, blinding, etc. Reasons for the choices the committee made will be explained and submitted to discussion. Critical comments that have already been received will also be considered.

The workshop is kindly sponsored by ECH, ECCH and LHMI.



Presenter Biographies

The workshop will be chaired by:

Ashley Ross, *Chair LMHI Proving Working Group & Associate Professor Durban University of Technology, South Africa*



Ashley Ross has been teaching homoeopathic philosophy and materia medica for 19 years. In addition, he is in private practice and engages in clinical and research supervision. He has a particular research interest in homoeopathic provings and proving methodology. In 2011 he completed a doctoral study investigating the relationship of proving data to the scientific and traditional African understandings of *Strychnos henningsii*. He has delivered lectures and seminars in South Africa, India and the UK, presented research papers at national and international congresses, and reviews for three international journals. He is an active member of the LMHI, and is Vice-Chairperson and representative for Homoeopathy on the Allied Health Professions Council of South Africa. In 2013 he completed a Postgraduate Diploma in Health Research Ethics and is a member of the University of KwaZulu-Natal Biomedical Research Ethics Committee.

Jean Pierre Jansen, *Co-ordinator ECH Subcommittee for Proving, Physician & Researcher*



Jean Pierre has been a physician for classical homeopathy and natural therapy's since 1986, based in Groningen, The Netherlands. He has been involved with provings since 1993 and is Co-ordinator of the Subcommittee for Proving of the European Committee for Homeopathy (ECH). He is a Researcher in proving methodology and peri-menstrual syndrome and Lecturer in CAM at the Medical Faculty, Groningen University. Jean Pierre is a physician for mentally disabled persons, as well as having a background working in occupational medicine.

Exhibitors



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Living Homeopathy Ltd., founded in 1994 by Aaron To Ka Lun, is a Homeopathy centre in Hong Kong which has over 190,000 patients registered. Living Homeopathy Ltd. has worked with the School of Homeopathy UK since 2008, translating their homeopathy courses into Chinese and delivering their attendance homeopathic practitioner course – the first in the Great China region.
www.living-homeopathy.com

Hong Kong Association Of Homeopathy (HKAH) was established as a legally registered non-profit professional organization in HKSAR in 2005 and joined the ICH in 2014. HKAH raises public awareness about Homeopathy, and recent Annual Conferences and Exhibitions attracted audiences of ~3000. HKAH has set up a registration system in 2005, and the Code of Ethics and Practice was established in 2008, Professional Conduct Procedures in 2013.
www.homeopathyhongkong.org

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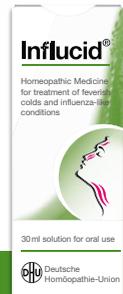
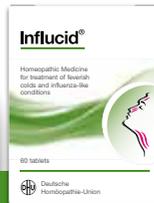
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Oral Presentations

Dr Klaus von Ammon

Fri 5 June, 10.00

Contribution of clinical observations to the discovery of mode of action of homeopathic medicines

Klaus von Ammon

Institute of Complementary Medicine IKOM, University of Bern

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Institute of Complementary Medicine IKOM, University of Bern
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Background: Mode of action of homeopathic remedies is subject of an intense dispute in conventional and homeopathic medicine. Observations in both, clinical and basic research are contradictory to considerations or ideas of plausibility.

Aim: To evaluate whether clinically observable facts gathered during case taking will contribute to the debate of mode of action of ultramolecular homeopathic medicines.

Method: Observations during consultations in homeopathic doctors' practice without intake or body contact of remedies will be presented and discussed.

Result: Clinically observable reactions of humans to non-material application of potentized substances are contradictory to the concept of a chemical or material mechanism of action of homeopathic remedies. These observations are compatible with an immaterial nature as mode of action in these remedies.

Conclusion: Study protocols to investigate the mode of action in homeopathic remedies should take an immaterial nature of this action into consideration and should therefore be designed appropriately.

Keywords: homeopathy, mode of action, practice, remedy, ultramolecular

Evaluation of Cytotoxic and Apoptotic Effects of Several Homeopathic Dilutions of *Echinacea angustifolia* on Human Breast, Cervical and Prostate Cancer Cells and Genotoxic Study of *E. angustifolia* MT

Delgado Pastelín Lucero, Ordaz Pichardo Cynthia, Gustavo Aguilar Velázquez

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Introduction: Cancer research needs a multi-disciplinary approach from several areas of medicine. The use of homeopathic drugs in cancer treatment has generated wide interest and controversy.

Objective: The aim of this research was to study the efficacy of homeopathic dilutions of *Echinacea angustifolia* on different cancer cell lines.

Methods: Cytotoxic activity of *E. angustifolia* mother tincture (MT) and homeopathic dilutions (6C, 30C, 200C, and 1M) was assessed on human cell lines: MDA-MB-231 (Breast cancer), HeLa (Cervical cancer) and PC-3 (Prostate cancer). Cytotoxicity was measured using the 3-(4,5-dimethylthiazolyl-2)-2,5-diphenyltetrazolium bromide (MTT) method¹. Apoptosis was determined by Annexin-V with flow cytometry². To demonstrate the safety of homeopathic dilutions, cytotoxicity was measured on peripheral blood mononucleated cells (PBMC). Genotoxicity was evaluated by Ames test³ (*in vitro*) and Micronucleus assay⁴ (*in vivo*).

Results: *E. angustifolia* homeopathic dilutions had a statistically significant decrease of cellular viability ($p < 0.05$ compared to the vehicle) on MDA-MB-231 cells. The viability percentages were MT (11.51 ± 0.81), 6C (24.21 ± 7.04), 30C (30.49 ± 9.22), 200C (24.86 ± 2.52), 1M (30.36 ± 2.61), vehicle (75.91 ± 3.64), and on HeLa cells were MT (3.71 ± 0.76), 6C (39.14 ± 10.6), 30C (45.81 ± 12.00), 200C (60.26 ± 10.16), vehicle (83.82 ± 11.56). The higher cytotoxic effects were observed with the MT on MDA-MB-231 cells, also in a lesser degree in all homeopathic dilutions. No cytotoxic effect was observed on PC-3 cells. The *E. angustifolia* MT induced death by early-apoptosis (48.6%) and late-apoptosis (34.4%) in MDA-MB-231 cells after 24h of treatment. On the other hand, the *E. angustifolia* MT was not mutagenic and had no genotoxic effect *in vitro* or *in vivo*.

Conclusion: This study provides scientific evidence of the ability of *E. angustifolia* homeopathic dilutions to induce apoptosis in the breast cancer cell line MDA-MB-231, which encourages a possible use as supportive medicines in cancer therapy. Further *in vivo* studies of these homeopathic remedies must be performed.

Keywords: *E. angustifolia*, homeopathy, cancer, cytotoxicity, apoptosis

Spatial allocation effects in a potentization basic research model – evidence for field-like effects of homeopathic preparations?

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Introduction: The mode of action of ultramolecular homeopathic preparations is still unknown. Interactions between objects or entities can be grouped in four main general scientific categories: material, force-/field-like, entanglement-like or informational. A field-like mode of action of homeopathic preparations would lead to treatment at a distance effects that are distance-dependent. We analysed a set of experiments with *Arsenicum album* 45x treated wheat seedlings regarding possible distance-dependent treatment effects.

Materials and Methods: We performed an *a posteriori* analysis of a set of 17 independent experiments with wheat seedlings pre-treated with 1‰ arsenic. Three treatments were applied (*Arsenicum album* 45x, water 45x, or unpotentized water) with 150 seedlings in each treatment group per experiment. Seedlings were arranged in hanging plastic bags side-by-side in identically treated blocks of 10 seedlings. The 3x15 blocks were coded and randomly allocated to the three treatments. Wheat shoot length was measured after 7 days. Treatment effects were analysed as function of spatial position of the seedlings.

Results: *Arsenicum album* 45x exerted an inhibiting effect (–3.2%, $p=0.01$) compared to both water and water 45x. Whilst the effect of *Arsenicum album* 45x on wheat-shoot growth was not dependent on the spatial position within the experimental arrangement, the water-control plants were smaller the closer they were to *Arsenicum album* 45x-treated seedlings.

Conclusions: The spatial pattern of the length of the water-control plants is compatible with the existence of a field-like effect of the homeopathic *Arsenicum album* 45x preparation. Another possible explanation, which cannot be ruled out by the present experiments, is contamination through the gas-phase. Future investigations of ultramolecular homeopathic preparations should control any such effects since they may mask treatment effects, leading to false-negative results. Closer investigation of the nature of this distance-dependent effect might contribute to identification of the mode of action of ultramolecular homeopathic preparations.

Basic research on homeopathic principles

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The homeopathic basic principles (Similia and dilution/dynamization) can be examined also using experimental animals and cell laboratory models. The cornerstone of homeopathy - that the whole clinical picture of the individual patient be taken into consideration - is not in dispute, but basic research also allow the action of drugs to be investigated in rigorous and reproducible settings. The effects of homeopathic remedies in cellular models are well documented for a wide range of dilutions/ dynamizations, albeit not all homeopathic effects can be reduced to the cellular level. Many of these effects have also been explained mechanistically as modifications of receptors, transduction mechanisms and gene expression changes. Recent evidence documents the ability of highly diluted compounds to modulate gene expression in human/animal cells and unicellular organisms. There are many possible mechanisms explaining the inverse effects of drugs, according to the different doses/dilutions and the changes in sensitivity and responsiveness of target systems. Hahnemann was the first to consider a primary and a secondary action of medicines, the latter being the opposite of the former. On the basis of these scientific facts, the logic of homeopathic reasoning is evident: if the body regulates itself in the opposite direction to the stimulus, we can use this property, giving low, sub-toxic, doses of pathogenic substances that trigger a counter-regulation. At a molecular level, pharmacology recognizes the classic distinction between allosteric drugs and orthosteric drugs. Orthosteric drugs bind to the active site of a target enzyme or a receptor and block it; allosteric drugs bind elsewhere on the protein and indirectly alter the conformations at the active site. In this perspective, homeopathic drugs may work by exploiting the characteristic features of allosteric regulation. The increasing credibility and plausibility of homeopathic ideas and experiences allows us to include this pharmacological approach in the mainstream of modern science.

Keywords: Basic research, laboratory models, inverse effects

Three Malaria studies in Kenya: a retrospective and prospective open label study and a comparison between homeopathy and coartem

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Background: Malaria still has in Kenya a high mortality and morbidity rate; this is coupled with rising resistance levels to the new standard drug coartem in several South Asian countries according to WHO reports. Homeopathy can be considered a form of individualized immune therapy and as such it deserves a place next to treatments focused at the microorganisms themselves. These factors require scientific evidence that may support its application in endemic diseases. We have developed a research line that comprises both qualitative and quantitative aspects of homeopathic management of malaria patients. The first two studies have been conducted in 2014, the third in 2015.

Aims: The first aim is the assessment of the management of homeopathically treated patients in several rural health care settings. This involved the treatment of malaria in the daily context of homeopathic clinics that also treat patients with other illnesses. We want to document how individualized homeopathy works within homeopathic clinics, not just conduct an isolated study in a context where homeopathy usually not is applied.

Material and methods: In a retrospective design in one clinic, the 2013-2014 rain season group of 54 malaria patients was assessed for classical malaria symptoms, homeopathic case taking, lab tests and prescription strategies. The prospective study in three clinics assessed the 2014 march-june rain season patients for the effect of homeopathic individual treatment. 86 patients were assessed and 69 completed follow up. All but one who returned for follow-up were negative for parasites. A drop-out analysis was made, indicating logistics as the main cause. In 2015 a comparative study is being made between the results of homeopathy and the standard treatment of co-artem. Both homeopathic and government clinic patients are participating.

Results: Results will be published in 2015 in peer-reviewed journals, indexed in Pub Med.

Feasibility and Clinical Results of a Pilot Trial of Individualized Homeopathic Treatment of Fatigue in Children Receiving Chemotherapy

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Background: We conducted this study from April 2012 to April 2014 examining the feasibility of a randomized trial of the homeopathic treatment for fatigue in children and youth receiving chemotherapy. Fatigue in this population is an area of interest due to the lack of effective interventions.

Methods: This was an open label pilot study of homeopathic treatment for fatigue in pediatric cancer patients treated at The Hospital for Sick Children (SickKids) in Toronto, Canada. Children (ages 2 to 18), diagnosed with any type of cancer who were receiving chemotherapy administered discontinuously in courses or cycles, were considered. Participants were given individualized homeopathic treatment for 14 consecutive days following a course of chemotherapy. Recruitment rates, adverse events and remedy selection were monitored and changes in fatigue was measured using the Symptom Distress Scale (SDS), the PedsQL Multidimensional Fatigue Scale and the PedsQL Generic Core Scales and Acute Cancer Module.

Results: 155 potential participants were assessed between April 2012 and April 2014. 45 patients were eligible to be approached, 9 consented to participate and eight participants received homeopathic treatment (one withdrawal prior to treatment). Eight participants completed 14 days of assessment. SDS scores, and proxy-report fatigue scores in general fatigue and sleep/rest fatigue had significant improvement. In spite of individualized case taking Cadmium Sulfuricum was the chosen remedy at the start of each case. One participant had a clinically observed homeopathic aggravation following a dry dose administration of a constitutional remedy.

Conclusions: In this setting, a future randomized trial of individualized homeopathy is not feasible for children with cancer for the purpose of fatigue reduction. There was a significant improvement of fatigue over the study period. Future study may consider an adult population, settings more familiar with homeopathy, or other study designs such as comparative effectiveness. The routine use of Cadmium Sulfuricum may be investigated.

Keywords: Homeopathy, Chemotherapy related fatigue, Cancer related fatigue, fatigue, Complementary medicine

Microimmunotherapeutic administration of cytokines improve the clinical symptoms in EAE an animal model of multiple sclerosis

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Experimental Autoimmune Encephalomyelitis (EAE) is one of the most used animal models in the study of Multiple Sclerosis (MS). EAE is induced by the injection of myelin proteins and specific adjuvants and leads to an important inflammatory process with activation of resident glial cells, principally microglia, which interact with infiltrated peripheral immune cells, mostly T-cells. In this context, and as described in MS, cytokines, play a crucial role in the cross-talk between these cell populations and in the modulation of the associated neuroinflammatory response. The main objective of our research is to interact in this process by modulating the immune response. Our work hypothesis is that the microimmunotherapeutic administration of specific combinations of cytokines closely related with the neuroinflammatory response may improve the clinical symptoms in EAE. To accomplish that, EAE was induced in C57BL/6 mice by injecting MOG₃₅₋₅₅ and Complete Freund's Adjuvant supplemented with *Mycobacterium Tuberculosis* and *Pertussis Toxin*. As control some animals were injected with saline. Both, MOG-injected and saline animals, were distributed in three groups: 1) without treatment, 2) treated with placebo and 3) treated with a stimulatory/inhibitory/modulatory combination of cytokines. The specific combination of cytokines and signalling molecules used in this study were: a) the pro-inflammatory cytokines IL-1_{beta}, IL-1r, TNF-_{alfa}, IL-12 and IFN-_{gamma} at inhibitory dilution (30CH), b) the anti-inflammatory molecules IL-1Ra, IL-10, IL-4, PGE2, TGF-_{beta} and IL-13 at stimulatory dilution (4CH) and c) the IL-6 cytokine at modulatory dilution (15CH). The clinical score of the animals were recorded daily and both the glial response and the infiltration of peripheral immune cells were evaluated using flow cytometry and immunohistochemistry. Our results clearly demonstrated that the group administered with the cytokine combination presented a delay in the onset of clinical symptoms and a significant reduction of the clinical score during the chronic phase of the disease. These clinical changes correlated with a reduction in the microglial activation pattern and a low number of lymphocytes (around 50%). In conclusion, our results suggest that the microimmunotherapeutic administration of specific combinations of cytokines, exert a beneficial effect in EAE progress and could be a very good strategy for modulating the neuroinflammatory response associated with certain CNS-diseases such as MS.

Keywords: Immune System, neuroinflammation, microglia, cytokines, microimmunotherapy, central nervous system, very low doses

Carbo animalis and immune response to Ehrlich ascites tumor in mice: an experimental model

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The quality of life in cancer patients is largely related to the activity of the immune system. Clinical reports show improvement in the quality of life of terminally patients treated with the homeopathic medicine carbo animalis, however, the literature on this subject is rare. The objective of this study was to propose an experimental model to study the possible effects of carbo animalis in the immune response to a highly malignant carcinoma, as well as their impact on the general condition of the sick animals. Male Balb/c mice were inoculated with Ehrlich ascites tumor and treated with carbo animalis 6cH or 6cH+30cH (potency association). The control group was treated with the same succussioned vehicle. Clinical signs, survival and the local immune response (peritoneal) were evaluated. T lymphocytes, B1 and B2, NK cells and phagocytes were identified and quantified by immuno-cytochemistry and flow cytometry. Animals treated with carbo animalis 6cH+30cH showed increase of incidence in clinical signs comparing to the other groups. The local immune response, showed increase in the proportion of CD25+ cells in relation to total T cells and increase of B1 cells compared to B2 cells in the group treated with carbo animalis 6cH. In contrast, animals treated with carbo animalis 6cH+30cH showed increase in the number of CD3+ cells and NK cells, both adhered to tumor cells. Although the clinical significance of these findings are still under discussion, this preliminary work provides a useful experimental protocol for the study of the mechanisms of this remedy and shows the possible relevance of homeopathic potencies association in the anti-neoplasm treatments.

Keywords: Ascites Ehrlich tumor, high dilutions, homeopathy, carbo animalis, tumor immunology, experimental oncology

Solvatochromic dyes detect the presence of homeopathic potencies

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Evidence will be presented which demonstrates that environment sensitive solvatochromic dyes can be used to detect the presence of the full range of homeopathic potencies through changes in their visible spectra. These dyes are characterised by possessing an oscillating dipole and it will be shown that this feature is essential for their interaction with potencies by comparison with structurally comparable non-solvatochromic dyes, which show no evidence of any sensitivity to homeopathic medicines.

It will be shown that changes in the spectra of solvatochromic dyes are due to the way these dyes aggregate, or order, in solution as a consequence of their interaction with potencies. Certain solvatochromic dyes appear to have their level of ordering enhanced by potencies, whereas others have their ordering diminished by potencies. A hypothesis which explains the results presented will be offered and suggests that homeopathic potencies themselves may be oscillating dipoles.

Implications for clinical practice and possible connections between the relevant dye chemistry and some clinically observed effects of homeopathic medicines will be explored in the light of the discoveries being made using these fascinating and informative dyes.

The chemistry involved will be kept as simple as possible for those with a limited chemistry background, whilst maintaining the level of scientific detail necessary for an understanding of the results presented.

Keywords: Solvatochromic dyes, homeopathic potencies, oscillating dipoles

A retrospective cohort study on the efficacy of homeopathy compared to homeopathy plus conventional medicine in the treatment of hypertension

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Hypertension currently affects nearly one billion people worldwide. It is a major cause of global morbidity and mortality, as well as a major risk factor of various chronic and fatal diseases. Individuals suffering from hypertension have increased over the years yet the rate of controlled blood pressure (< 140/90 mmHg) remains poor. While the demand for traditional, complementary and alternative medicine (T/CAM) is on the rise, more evidence is needed to evaluate whether the clinical use of homeopathy will bring any beneficial effects to the community at large. The aim of this retrospective cohort study is to evaluate the effects of homeopathic treatment compared to integrated treatment using homeopathy plus conventional pharmacotherapy in terms of blood pressure control, in order to determine its efficacy in the treatment of hypertension. Data was collected at the National Academy of Homoeopathy, India (NAHI) located in Nagpur, Maharashtra. Cases diagnosed and treated for hypertension in 2013 under the outpatient department affiliated to Shaad Homoeopathic Hospital Complex & Research Centre were assessed for eligibility, classified and analyzed. A total of 41 subjects were selected and classified into homeopathy group (N=22) or integrated group (N=19) according to the treatment they received. Statistical results with repeated measures ANOVA suggest that there is no significant difference between the homeopathy and the integrated group in terms of blood pressure reduction at week six of treatment. It is concluded that homeopathy on its own is as efficacious as homeopathy plus conventional pharmacotherapy in the treatment of hypertension.

Keywords: Hypertension, homeopathy, integrated treatment

Different approaches in homeopathic basic research: plant-based bioassays and evaporation-induced crystallization

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Two different approaches can be adopted in fundamental research in homeopathy to evaluate the effectiveness of homeopathic preparations: i) plant-based bioassays and ii) evaporation-induced crystallization. As concerns i), the classic test of wheat germination and growth has been quoted as a basic model for research on homeopathic potencies. Results of our experimentations showed that As_2O_3 45x (As 45x) induced a significant increase of germination rate and stalk growth with respect to control. This simple model was used also to study the following aspects:

- effect of temperature: results show that As 45x heated at 20 , 40 and 70 C induced a significant increase of germination rate vs. control, losing its effectiveness at 100 C
- effect of aging-time: As 45x always induced a stimulating effect on germination, significant only after three months from treatment preparation
- effect of succussion number: a significant increase of germination was obtained starting from 32 succussions between each dilution step for As 45x
- effect of serial dynamizations (from 5x to 60x): data showed an oscillatory trend, with some potencies inducing a significant decrease (35x), while others a significant increase of germination rate (5x, 30x, 40x, 45x, 55x, 60x)
- effect on gene expression profiles: a massive reduction of gene expression levels to values comparable to those of the control group, induced by As 45x, was observed for several functional classes of genes.

The second approach sought to verify whether the droplet evaporation method (DEM) can be applied to assess the effectiveness of homeopathic remedies. We studied the shape characteristics of the polycrystalline structures formed during droplet evaporation of wheat seed leakages. The results showed that As 45x increased the local connected fractal dimension levels and bilateral symmetry exactness values in the polycrystalline structures, as compared to the water treatment.

Keywords: Plant-based bioassays, droplet evaporation method, wheat seeds, arsenic trioxide 45x

Replication of Specific Effects of a *Stannum Metallicum* 30x Preparation in a Cress Seedling/ Biocrystallization Test System

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One of the aims of basic homeopathic research is to reveal any specific mode of action of potentized preparations. This requires stable and reliable preclinical tests measuring either specific physicochemical properties or biological effects of homeopathic preparations.

Within a precursor project, we developed a bio-assay which yielded highly significant evidence for specific effects of an ultra-molecular *Stannum metallicum* 30x preparation relative to *Water* 30x, based on 15 independent randomized and blinded experiments performed at two independent laboratories. The test system is based on cress seed germination, biocrystallization and subsequent computerised image analysis of the biocrystallization patterns. The biocrystallization method is based on the phenomenon that self-organizing, additive-specific crystallization patterns emerge when a $\text{CuCl}_2 \cdot 2\text{H}_2\text{O}$ solution with additives is crystallized on a glass plate. The method acts as an indicator for systemic properties of the applied additive.

In the present project we investigated the reproducibility of the effects found in repeated experiments based on improved methodology towards: (i) optimization of the laboratory procedures to avoid any processing order effects, (ii) full implementation of blinded systematic negative control (SNC) experiments, and (iii) *Water* 30x was replaced by *Lactose* 30x to control for the trituration of *Stannum metallicum*. In total 10+10 independent randomized, coded experiments were performed in two independent laboratories. In addition, 10+10 SNCs were performed to control experimental stability.

Meta-analysis of the data revealed the same data structure in both projects, i.e. a reproduction of the significant differences between the two homeopathic preparations. The SNCs showed no significant intra-day, inter-day or inter-lab differences, indicative of a robust and reproducible test system. We were thus able to establish a test system yielding reproducible biological effects of an ultra-molecular homeopathic preparation. These ground-breaking results point to a promising potential of the method to contribute to basic homeopathic research.

Keywords: Bio-assay, systemic properties, *Stannum metallicum* 30x, systematic negative control experiments, reproducible effects

The role of the research ethics committee in providing ethical approval for provings. The findings from a pilot study

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Background: Provings are considered to be a cornerstone of homeopathic practice. Stuart Close notes how Hahnemann “instituted “provings” of drugs upon himself, members of his family, friends, students and fellow practitioners, keeping all under the most rigid scrutiny and control, and carefully recording every fact and the conditions under which it was elicited’. This situation has remained constant over the years, with the majority of provings being conducted in the many homeopathy schools and colleges. Whilst the methodology employed in carrying out provings has developed over the last two decades, they have not generally been subject to a process of ethical review.

Aims: The presentation will commence with an examination of the ethical issues inherent in provings, before moving on to an analysis of the results and experience of taking a proving to a research ethics committee for ethical approval. The presenter, who is Chair of a Research Ethics Committee, will share the issues encountered and solutions found along the way, and will discuss the experience of both the research ethics committee and the proving organisers. The project offers an insight into how provings could be conducted in a way that is both congruent with the values of the profession and meet the requirements of research in the twenty-first century.

Keywords: Provings, research ethics committee, homeopathy

Repetitions of fundamental research models for homeopathically prepared dilutions beyond 10⁻²³: a bibliometric study

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Introduction: Repeatability of experiments is an important criterion of modern research and a major challenge for homeopathic basic research. In 2010 we presented an overview [1,2] about basic research studies in high homeopathic potencies that have been subjected to laboratory-internal, multicenter or independent repetition trials. This overview was now updated.

Methods: We considered biochemical, immunological, botanical, cell biological and zoological studies on high potencies, i.e. beyond a dilution of 10⁻²³. Main sources of information were reviews, personal contact with members of the homeopathic basic research community, and the MEDLINE and HOMBREX databases. Studies were extracted from the publications and grouped into models. Studies were further sorted according to repetition type (laboratory-internal, multicenter, or independent) and results achieved.

Results: In 2010, a total of 107 studies have been found. From these, 30 were initial studies. In the attempt to reproduce one of these initial studies, 53 follow up studies yielded comparable effects (35 laboratory-internal, 8 multicenter, 10 independent repetitions), eight studies showed a consistent, yet different result from the initial study (2 laboratory-internal, 2 multicenter, 4 independent repetitions), and 16 studies yielded zero effects (5 laboratory-internal, 2 multicenter, 9 independent repetitions). When all repetitive studies are considered, 69% reported effects comparable to that of the initial study, 10% different effects, and 21% zero effects. Independently performed repetition studies reported 44% comparable effects, 17% different effects, and 39% zero effects. The update brought to the forth further studies, with approximately the same distribution regarding the categories.

Conclusions: We identified more than 20 experimental models in basic research on high homeopathic potencies, which were repeatedly investigated. Most of these were reproduced with comparable results, about ¼ were also reproduced with different results, and other repetitions showed no results for more than half of the models. We encourage further repetition trials of published studies, in order to learn more about the model systems used and in order to test their repeatability [1,2].

Keywords: Homeopathy, high dilutions, repetition, review, bibliometric

The clinical experience in the centre of integrated medicine , Pitigliano hospital using magistral homeopathic formulations: results in outpatients affected by chronic diseases and considerations on the chronic care model integrated with homeopathic approach

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This work aims to assess the rationale and the results of an integrated homeopathic protocol applied in the Ambulatory of a public Hospital for the treatment of chronic diseases among 1600 patients: we have classified them by age, sex , kind of chronic diseases and we have considered also the incidence of comorbidities; we have assigned an integrated protocol comprehensive of a magistral homeopathic formulation different for any conditions. Then we have collected the results after a fixed time of observation (different for any kind of disease) using Edmonton scale , SF12, family and work performance evaluations.

Results: Recurrent respiratory syndromes :85% reduction of the use of conventional therapies (antibiotics, antiasthmatics, cortisonics) ; 75% in symptom reduction (at the start and then after 2 months)

- Rheumatic syndromes : reduction of pain (from 55% to 85%) ; reduction in the use of conventional drugs (after two months 28% less; after 4 months 57% less)
- tinnitus (reduction of 45% symptoms based upon visual analogic scale)
- Allergic syndromes (75%-100% reduction of symptoms ; reduction in the use of conventional therapies: 75% in perennial allergies and 100% reduction in seasonal allergies);
- Chronic pain syndromes (such as headache, migraine, etc.): (reduction of pain from 45% to 84%, depending upon the different pain syndromes).

Our experience confirms the possible role of homeopathy in chronic diseases as longlasting therapy, useful to take into account the full complexity of this kind of patients and to try to discharge, when it is possible, the use of conventional drugs.

Homeopathy and public health: Multimorbidity, polypharmacy, antimicrobial resistance, adverse drug reactions and homeopathy

Peter Fisher

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Editor-in-Chief, Homoeopathy

Multimorbidity and the linked problems of polypharmacy, adverse drug reactions and antimicrobial resistance are among the greatest challenges facing public health in the UK and all developed countries. I have given evidence to the House of Commons Health Committee and to the Commons Science and Technology Committee on these issues. In low income countries infectious diseases remain a major challenge, often linked to antimicrobial resistance. There is growing evidence, particularly from clinical effectiveness studies, that homeopathy has potential to alleviate this crisis.

I will overview the evidence around the incidence, nature, correlates and consequences of multimorbidity. Also the connected issues of antimicrobial resistance, polypharmacy, adverse drug reactions and drug interactions.

I will then review the clinical evidence for homeopathy, focussing on comparative effectiveness research into its potential to reduce consumption of antibiotics and other undesirable treatments. This includes evidence that integrating homeopathy into primary care reduces prescriptions of potentially harmful medication for upper respiratory infections and musculoskeletal conditions with equivalent or greater clinical benefit. Integrating homeopathy is also associated with healthier lifestyles and greater participation in self-care.

I will also review the emerging evidence for homeopathy as an adjunctive treatment in life threatening infectious diseases in developing countries, including malaria and multiple drug resistant TB.

If homeopathy is to realise these opportunities to contribute to public health, a clear and focused strategy is required. Networks and collaboration must be developed; irresponsible and speculative claims must be avoided. Instead we should concentrate on well-established treatment strategies and explore the potential of constitutional treatment in multimorbidity, treating people as individuals with complex health problems, not as multiple diseases each to be treated with different, and often multiple, drugs.

Homoeopathic management of Attention Deficit Hyperactivity Disorder: A randomized placebo controlled pilot trial

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Objective: To evaluate the usefulness of individualized homoeopathic medicines in treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Design: Randomized placebo controlled single blind pilot trial.

Setting: Central Research Institute (Homoeopathy), Kottayam, Kerala, India from June 2009 to November 2011.

Participants: Children of 6-15 years meeting DSM-IV criteria for ADHD.

Interventions: 61 patients (Homeopathy=30, placebo=31) were randomized to receive either individualized Homoeopathic medicine in LM potency or placebo for a period of one year.

Outcome measures: Conner's Parent Rating Scale-Revised: short, Clinical Global Impression-Severity Scale (CGI-SS), Clinical Global Impression-Improvement Scale (CGI-IS) and Academic performance.

Results: 54 patients (Homeopathy=27, Placebo=27) were analyzed under modified ITT. All patients in Homeopathy group showed better outcome in baseline adjusted GLM repeated measures ANCOVA for oppositional, cognition problems, Hyperactivity and ADHD Index(domains of CPRS-R(S)) and CGI-IS at T3,T6,T9 and T12 ($p=0.0001$). The mean baseline-adjusted treatment difference between groups at month 12 from baseline for all individual outcome measures favored homeopathy group; Oppositional (-16.4, 95% CI -20.5 to -12.2, $p=0.0001$), Cognition problems (-15.5, 95% CI -19.2 to -11.8, $p=0.0001$), Hyperactivity (-20.6, 95% CI -25.6 to -15.4, $p=0.0001$), ADHD I (-15.6, 95% CI -19.5 to -11.6, $p=0.0001$), Academic performance 14.4%, 95% CI 8.3 to 20.5, $p=0.0001$), CGISS (-1.6, 95% CI -1.9 to -1.2, $p=0.0001$), CGIIS (-1.6, 95% CI -2.3 to -0.9, $p=0.0001$).

Conclusion: This pilot study provides evidence to support the therapeutic effects of individualized homeopathic medicines in ADHD children. However the results need to be validated in multicenter randomized double blind placebo controlled clinical trial.

Keywords: Homeopathy, RCT, ADHD, placebo

Proving Ethics: At the coalface

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Background: Debate has emerged over the need to put proving's through formal ethics processes. No one argues that we should have ethical provings. But the process is at question, as in some countries there are significant hurdles to robust homeopathic research, unsympathetic ethics boards, and poor understanding of provings in general. Further, many have argued that by doing this kind of research, homeopathy is losing control of its ability to direct the narrative.

Concerns have been raised about the clinical relevance of many modern provings, health of provers, safety, adverse reaction processes, exit processes, prover coercion etc. In some countries (US, South Africa, Australia) thorough ethics processes have been put in place, sometimes constraining but more often, creating better and more transparent proving processes. Concurrently, proving guidelines are being discussed and re-written at the professional level.

Method: Endeavour College has previously put homeopathic provings to an ethics board. While successful each time there were significant discussion points, conflict, compromise and adaptation to the process depending on the substance involved and the make up of the panel.

Results: Endeavour College now has 5 completed proving's that have moved through this ethics process. In some years the successful submission has only been possible by;

- Re-proving existing substances
- Clearly naming the remedy beforehand
- Guaranteeing students could not be coerced or participate at all
- Altering conventional proving method

This paper goes into the specifics of the response when challenged by the ethics board.

Discussion/conclusion: For the successful navigation of a proving through a formal ethics process, flexibility, listening, adaptation, agility and persistence are required to bring a trial home. Even with this rigorous ethics process a successful clinically relevant proving cannot be guaranteed. Excellent method and supervision is also necessary, but a transparent ethics approval process is a fundamental and important step in the process.

Homeopathic treatment of respiratory illnesses in children: Results from two randomized trials

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These studies were done to determine if homeopathic preparations are useful in the treatment of URI's in children, especially when there are no conventional treatments available and/or antibiotics are to be avoided. In the first study, children 6 months – 11 years old, diagnosed with AOM and managed with a delayed antibiotic approach, were randomized to standard therapy alone or standard therapy plus a homeopathic ear drop preparation. The primary outcome was whether or not an antibiotic prescription given at the index visit was filled; any antibiotic use was a secondary outcome. During the 12-15 day follow-up period, significantly fewer parents of children randomized to the homeopathic ear drops group filled the antibiotic prescription compared to those of children receiving standard therapy alone (26.9% and 41.2%, respectively, $P = .032$). In the second study, children ages 2– 5 years old diagnosed with upper respiratory infection were randomized to receive a homeopathic combination product for cold and cough or a placebo. Parents were instructed to give a dose of study medication as needed for relief of URI symptoms up to 6 times per day for three days. Parents recorded changes in symptoms 1 hour after each dose, as well as changes in overall severity of URI symptoms in twice daily diaries. There was no difference in symptoms one hour after the dose between those receiving the homeopathic preparation compared to placebo. However, the homeopathic group reported a statistically significant improvement in 3 of the 4 URI symptoms at 12 and 24 hours after enrollment as well in a composite cold score. These studies should encourage health care providers to utilize homeopathy as an alternative to conventional therapies in the treatment of URI's in children.

Keywords: URI, acute otitis media, homeopathic combination products

Homeopathic Pathogenetic Trials (provings) do not always match homeopathic clinical practice. Possible answers from the qualitative research tradition.

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Traditionally, Homeopathic Pathogenetic Trials (HPT, proving) are published following the head to toe schema. This is a relatively easy format for the unprejudiced observer. It leads to the first cured cases if one applies the analytical methods of a few 19th century authors. Thus the materia medica of that remedy is enriched and extended. This cyclic process that ideally arrives at a saturated, generally accepted remedy picture is called clinical verification.

However, since the early 1990's new analytical procedures developed in clinical work (e.g. Sankaran: basic delusion, vital sensation; Sherr: dynamic verb; Scholten: groups; Yakir, Scholten: plant taxonomy; Vervarcke: vital approach; Whitmont, Lilley, Cicchetti: archetypes; etc.) have been (re-)introduced. The C4-approach seems the only system embedded in a particular proving design. These developments pose the question, if the traditional proving method still matches modern clinical work.

The new analytical methods can be applied at various stages of the materia medica knowledge formation process: a) during data collection in provings, where instructions for provers and supervisors may reflect one or another new approach, b) during analysis of the proving symptoms after data collection, defining the remedy-image for the first clinical verification cycle, and c) at various moments during the clinical verification phase. It is unclear, whether the observer can and should keep an unprejudiced position (Hahnemann, 1835) in all instances.

Qualitative research is a research tradition (mainly in ethnology, sociology, psychology, nursing) that has developed multiple procedures dealing with this problem and can enhance and may support the quality and credibility (validity) of qualitative research, such as provings. This presentation gives an overview of questions, viewpoints and methods that provide directions to improve proving methodology.

Keywords: Proving methodology; Homeopathic Pathogenetic Trials; Clinical verification; Qualitative research.

A Randomized Open Comparative Clinical Trial on the Effectiveness, Safety and Tolerability of a Homeopathic Medicinal Product for Frequent Acute Upper Respiratory Tract Infections in Children

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Background: Homeopathy may be an effective alternative for antibiotics in the treatment of recurrent upper respiratory tract infections (URTI) in children. More research is warranted to further explore this potential.

Objective: To investigate the effectiveness, safety and tolerability of the homeopathic product Immunokind, in children for the prevention of recurrent URTI in comparison to another homeopathic product.

Design: A prospective, multicenter, randomized, open, comparative clinical study with two parallel treatment groups at four outpatient pediatric clinics in Russia.

Methods: Children aged \leq six years with susceptibility to URTI (\geq three occasions during the last six months) were enrolled from February 2010–September 2011 in the study. They were randomized to receive for three weeks either Immunokind tablets (intervention group) or Aflubin tablets (control group), with a six months post-treatment follow-up period. Exclusion criteria were acute URTI, the exacerbation of chronic URTI and severe comorbidity. Primary effectiveness endpoint was change in the frequency of URTI after three and six months of follow-up compared to baseline frequency of URTI (last 12 months prior to study). Secondary endpoints were changes in total complaints, symptoms scores, antibiotic use, treatment satisfaction, tolerability and safety.

Results: A total of 201 children (100 in intervention group, 101 in control group) were randomized. Mean age of children was 34.2 ± 20.0 months (intervention group) and 35.8 ± 19.9 months (control group). Preliminary analysis demonstrated that the number of URTI decreased after six months post-treatment compared to baseline (last 12 months prior to study start), both in the intervention (6.5 ± 2.3 to 2.1 ± 1.6) and control group (6.4 ± 2.2 at baseline to 2.5 ± 1.4). Analysis with respect to concomitant antibiotic use and other outcome parameters is ongoing and will be presented at the conference.

Conclusions: Immunokind tablets appeared to be effective in preventing recurrent URTI.

Keywords : Respiratory tract infections, children, homeopathy, safety, antibiotic use

Results of an International, Randomised, Controlled Clinical Trial with a Complex Homeopathic Medication in Feverish Upper Respiratory Tract Infections

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Background: Complex homeopathic medications are an opportunity to introduce homeopathy in countries without homeopathic tradition and in cases where daily routine doesn't allow homeopathic repertorisation for an individual therapy. We set out a clinical trial to investigate the effectiveness and safety of the complex homeopathic medication Influcid® as add-on therapy to usual care in patients suffering from upper respiratory tract infections (URTI), the most frequently occurring illness in the world with great impact on health economics in terms of missing days at work.

Methods: Between Nov 2010 and Apr 2011 we conducted a randomised, controlled clinical trial in Germany and Ukraine. Patients aged 1-65 years with URTI were included. To all patients standard symptomatic medication (Paracetamol, Ambroxol and/or Oxymetazoline) was offered on demand depending on their symptoms. The test group received additionally Influcid (active ingredients: Aconitum D3, Bryonia D2, Eupatorium perfoliatum D1, Gelsemium D3, Ipecacuanha D3, Phosphorus D5) for seven days. The Wisconsin Upper Respiratory Symptom Survey (WURSS-21) was used to assess URTI symptoms. Primary outcome measure was the response at day 4, defined as the absence of fever and the absence or very mild degree of URTI-symptoms.

Results: 523 patients (265 test and 258 control group) were randomised in 22 centres. Response at day 4 differed highly significantly in favour of the Influcid-group (15.4% vs. 6.7%, Δ 8.7%; 95%-CI: 2.9-14.5%; $p=0.0018$; χ^2 -Test). Dosage and duration of symptomatic treatment was significantly lower and symptoms alleviated 1-2 days earlier in the Influcid group. Eleven adverse events were classified as probably or possibly treatment related: one adverse event was possibly related to Influcid (vomiting) and ten to the symptomatic therapy.

Conclusion: The study data suggest Influcid as a therapeutic option in the treatment of URTI as it effectively reduced URTI symptoms and the need for conventional symptomatic treatment and was well tolerated.

Keywords: Upper respiratory tract infections, fever, randomized controlled clinical trial, homeopathy, complex homeopathic medication.

Effect of Ultra-high Dilutions of *Lycopodium clavatum* on Reproductive and Sexual Functions in Aged Male Wistar Albino Rats

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Introduction: Ultra-high dilutions of *Lycopodium clavatum* (LC) is commonly used in the homeopathic treatment of various disorders in male reproductive system. This efficacy of LC in alleviating male reproductive system disorders is exploited in this study on a reproducible, natural, animal experimentation model of ageing to ascertain the pharmacodynamics of homeopathic ultra- high diluted medicines.

Methods: Aged male wistar albino rats were grouped randomly into six groups (n=6), where the 2nd, 3rd, 4th and 5th group animals were treated with LC Q, 6C, 30C and 1M respectively. 1st group served as aged control and 6th group served as vehicle control. LC was given at a dose of 20µl/animal/day per-orally for 60 days. Estimation of serum testosterone was done at the beginning and end of the experiment. After 60th day, of testis and epididymis were analyzed. Following sperm parameters were studied viz., Viability, Concentration, Motility, Morphology, Morphometry, Acrosomal intactness, Membrane permeability (HOST) and Nuclear condensation (AO-Assay). Testicular Enzymic, Non-Enzymic antioxidants and Lipid peroxidation were analyzed. Test for potency and mating behavior assessment was done every 30 days till the end of the study. Results were statistical analyzed.

Results and Discussion: Testosterone levels were increased in drug treated animals. Sperm parameters of drug treated groups were significantly better compared to the aged control and vehicle control groups. Histopathology examination revealed a better spermatogenic status in the treatment groups than the control groups. Mating behavior assessment and test for potency showed better sexual performance in drug treated groups than control groups. Among the drug treated groups, 30C and 1M treated groups showed significant better results compared to Q and 6C treated groups.

Conclusion: Efficacy of LC in sexual sphere was confirmed using a stable animal model i.e. aging. Effectiveness of LC was further appreciated in ultra-high dilutions compared to its lower dilutions.

Keywords: Homeopathy, *Lycopodium clavatum*, aging, andrology, sperm, rats

Exploring the model of murine infection by *Trypanosoma cruzi* to investigate treatment with highly diluted drugs: the influence of *Lycopodium clavatum* or Phosphorus in Wistar rats

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Research using highly diluted drugs has advanced significantly with increasing number of consolidated research groups. This work evaluates the influence of highly diluted *Lycopodium clavatum* or Phosphorus in Wistar rats infected by *T. cruzi*. The experiment was conducted as a blind, controlled and randomized by draw assay and was approved by university ethical committee. 75 male rats (*Rattus norvegicus*, Wistar lineage), 45 days old, intraperitoneally inoculated with 5×10^6 *T. cruzi* Y-strain blood trypomastigotes were divided into three groups: IC (infected control group, treated with 7% hydroalcoholic solution), Ly (infected treated with *Lycopodium clavatum* 13CH), Phos (infected treated with Phosphorus 13 CH). All treatments were offered ad libitum on the second day before the infection, and on the second, fifth and seventh day after infection, provided for 16 consecutive hours. Evaluated parameters: weight, temperature, water and food intake, amount of excreta, intestinal length and diameter, hair aspect, stool consistency, heart and respiratory rates, pre-patent period, parasitemia peak, total parasitemia, evaluation of myenteric neurons, inflammatory infiltrate and cytokines production. Data were statistical compared. *Lycopodium* and Phosphorus have significant beneficial effects on the clinical evolution of the treated animals. No significant difference was observed for any parasitological parameter evaluated. Ly and Phos groups showed protection of distal colon neurons numbers. In the heart, liver and intestine animals treated with *Lycopodium* and Phosphorus showed significant less inflammation compared to IC. In striated skeletal muscle, Phosphorus animals showed the number of inflammatory foci higher than IC. In a sequential evaluation, IL1- α , IL1- β , IL4, IL6, IL10, IL12, TNF- α , IFN- γ and GM-CSF levels varied significantly different for *Lycopodium clavatum* and Phosphorus. The homeopathic treatment with *Lycopodium clavatum* or Phosphorus medicines (13CH) promoted, in a different way, beneficial effects on several parameters evaluated in *T. cruzi* infection of Wistar rats. The treated groups establish balance of host-parasite relation differently, with lower cell and tissue damage to the infected host. *Lycopodium clavatum* and Phosphorus modifies the animals' immune response, promoting less inflammation and protecting the intestine, preserving the myenteric neuronal population.

Keywords: *Trypanosoma cruzi*, clinical evaluation, myenteric neurons, cytokines, homeopathic medicine, *Lycopodium clavatum*, Phosphorus

Systematic review and meta-analysis of randomised, placebo-controlled, trials of individualised homeopathic treatment

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Background: The BHA's programme of systematic reviews of randomised controlled trials (RCTs) of homeopathy distinguishes key attributes of study design and intervention: placebo controlled *cf.* other-than-placebo controlled; individualised *cf.* non-individualised homeopathy; treatment *cf.* prophylaxis.

Objective: This presentation centres on the hypothesis: For the broad spectrum of medical conditions that have been researched using RCTs, the main outcome of an individualised homeopathic treatment approach using homeopathic medicines is distinguishable from that of the same approach using placebos (i.e. individually prescribed homeopathic medicines have specific effects). The impact of internal validity (risk of bias, RoB) and model validity (MV) informed the detailed interpretation of results.

Methods: 31 papers (reporting a total of 32 RCTs) were eligible for systematic review. For each trial, the separate ratings for RoB and MV were merged to obtain a single overall designation ('high', 'moderate', 'low' or 'very low' quality). The identified main outcome measure was extracted, if possible, for each trial and used in meta-analysis.

Results: Combining assessment of MV and RoB identified 3 trials of 'high quality', 8 of 'moderate quality', 18 of 'low quality' and 3 of 'very low quality'. This hierarchy was little different from that attributed to RoB alone, and so the meta-analysis findings were essentially unchanged by accommodating MV: a small, statistically significant, pooled odds ratio (OR) favouring homeopathy (mean = 1.53; N = 22) that is robust to sensitivity analysis based on best evidence (mean OR = 1.98; N = 3). There was no association between a trial's MV and RoB or direction of treatment effect.

Discussion: Accommodating MV in the quality appraisal of RCTs does not alter the conclusion that individually prescribed homeopathic medicines may have small, specific, treatment effects. This conclusion reflects evidence in individualised homeopathy across a broad spectrum of medical conditions and thus transcends condition-specific analysis.

Keywords: Individualised homeopathy, meta-analysis, randomised placebo-controlled trials, systematic review

Effects of homeopathic *Arnica montana* on gene expression of human macrophages-results of quantitative real-time PCR

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Introduction: *Arnica montana* is a plant belonging to the Compositae family and one of the most popular medications used in complementary and homeopathic medicine to treat inflammation, wounds, hematoma, contusion and pain. Recently has been pointed out the double role of the sesquiterpenic lactone helenalin in the inhibition of the transcription factor NF-KB directly targeting p65 and in the gene suppression of the same subunit. This study considers the changes due to different homeopathic dilutions in gene expression of several cytokines, chemokines and receptor by real-time PCR technique in monocyte/macrophage cellular model.

Methods: The effect of *Arnica m.* on gene modulation of human monocytes (THP-1 cell line) was analyzed with RT-ARRAY PCR technique. THP-1 cells differentiated into activated macrophages by phorbol-12-myristate-13-acetate (PMA) for 48h were challenged with different homeopathic dilutions of *Arnica m.* (2c, 3c, 5c, 9c and 15 c diluted/dynamized in water, with 0.03% ethanol final concentration) and with control solution (water with 0.03% ethanol). Drug-treated and untreated macrophages were incubated for 24 h in the absence and in the presence of 10 ng/ml E. Coli lipopolysaccharide (LPS). Total RNA was extracted and retro-transcribed into cDNA to quantify the relative amount of gene transcripts (SYBR Green dye) in treated cells respect to placebo (DDCt method).

Results and Discussion:

The treatments with *Arnica m.* homeopathic dilutions in cell cultures without LPS induced a significant changes in gene expression modulation for the CCL2 (Freg=-40%), IL-1B (Freg=-50%) and TNF-a (Freg=-25%), compared with vehicle solution. The effect was not linearly related to dilution/dynamization, showing a pattern of down-regulation genes in all dilutions tested, with the exception of 15c. Different patterns were observed in the presence of LPS, where only BMP2 gene resulted slightly up-regulated (Freg=+20%). Our findings are compatible with a mild modulation of inflammatory process by homeopathic dilutions/dynamizations of this plant, even if further studies are needed to clarify the molecular targets.

Investigation of effects of highly diluted substances in periodontal inflammation using flow cytometry analysis – A pilot study

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Background: Homeopathic drugs are applied in complementary treatment of periodontal inflammation. However, less is known about the basic working principles of highly diluted remedies in such chronic inflammatory conditions. We therefore aimed at investigating the in vitro effects of highly diluted substances in periodontal inflammation by using fluorescence-activated cell sorting (FACS) analyses.

Material and Methods: CD4+ lymphocytes were extracted from blood samples of three patients suffering on chronic aggressive periodontitis and three matched healthy volunteers and mixed with potentized diluted aquaeous extract (D12 and C200) from Mercurius solubilis, Silicea, Sulphur, Tuberculinum, or a placebo. Activation patterns were then analyzed by means of the density of temporary expression of surface markers CD25 and CD45R0 in FACS. Statistical analyses were performed using descriptive statistics and correlation analysis.

Results: In total, the potentized aquaeous extracts yielded to a variety of effects both with respect to the lymphocytes of healthy volunteers vs. periodontitis patients, as well as to the potencies used (D12 vs. C200). Only Mercurius D12, Silicea C200 and Sulfur D12 showed similar activation patterns of CD25 and CD45R0 markers while all other substances did not provide concordant response. Of these three substances, Sulfur D12 showed the highest change in expression of CD45R0 markers in the healthy volunteers (+35.39%) as well as in patients (+36.47%). This was also confirmed in the analysis of CD25 expression.

Conclusion: Discussion about the basic working principles of highly diluted substances is still vital and leads to controversies in the scientific discussion. Although conclusions are limited due to low sample size, our pilot study was able to reproduce former results on lymphocyte migration activity with Sulphur D12.

Keywords: CD 4 lymphocytes, FACS analyses, chronic aggressive periodontitis, Sulphur D12

Homoeopathy in iatrogenic disorders

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Emergency is potentially life threatening. Massive increase in their number is posing serious threat to the patients' safety, resulting in mortality outcome. Homoeopathy can play an important role in the treatment of acute and urgent aspects of illness resulting from mechanical, psychological injuries or other reasons. Modern experts and common man says, "Homoeopathic medicine in emergency???" Not at all possible with homoeopathy!!!

It shows their inadequate knowledge in the field of homoeopathic system of medicine. A scientific clinical research work was done on 2100 cases during a span of 1993-2013, with great success and enthusiastic result on Neurological –Cerebrovascular accident-Hydrocephalus, Status epilepticus (25%), Cardiovascular-Angina pectoris , Myocardial infarction, Congestive heart failure (20%), Respiratory –Status Asthmaticus (10%) , Gastrointestinal-Gastro intestinal bleeding (20%), Renal-Acute renal failure,uraemic coma (25%) emergencies when intensive, surgical and transplantation methods were indispensable.

Pathological, radiological, ultra sonological and endoscopic investigations were conducted to identify the internal status of the disease. Script, law of similar remains the same. Application changes, similimum selected after inspection, observation and etiology of disease and administered with correct potency, brings instant relief in majority of cases. Medicines acted like a rescue officer were Aconite Nap (1%), Arnica M (n=8 %), Ars Alb (n=18 %) Apis Mel (n=18%), Cactus G (n=16%), Helleborus N (n=5%), Opium (n=10%), Phosphorus (n=16 %), Plumbum met (n=2%), Spigelia (n=6%)

Results were outstanding with ninety percent success in majority of cases whereas uraemic coma and cerebrovascular accident patients were saved with a success rate of sixty percent.

Therefore, accept challenges of emergencies. Nourish the brain with knowledge of disease, materia medica, Organon and apply it intelligently. Minute observation, quick decision, striking at the correct symptom, results will be outstanding.

Keywords: Homoeopathy, surgery, clinical research, emergency

How safe is homeopathy? An analysis of the Posadzki et al. 2012 safety paper and fresh review of the same literature

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Background: When considering the relative value of any medical intervention, safety is of paramount importance, yet until recently there has been limited exploration of the safety of homeopathy. Homeopathic medicines are commonly considered to carry a low risk of causing serious side-effects – a view supported by two systematic reviews (Dantas & Rampes, 2000; Bornhöft & Matthiessen, 2011).

However, in 2012, a systematic review of case reports and case series by Posadzki et al. claimed to have identified 1159 patients who experienced mild-to-severe adverse effects (AEs), caused either directly or indirectly by homeopathic treatment, including four fatalities. This paper attracted criticism not because of its findings that homeopathy could cause harm – this is to be expected of any medical intervention – but because of the poor quality of the paper itself. Multiple flaws including misreporting, inaccuracies and the inclusion of cases which did not involve homeopathy, were discovered.

Methods: In this review we re-analysed all 37 primary articles identified by Posadzki et al. (35 case reports/case series and 2 reports from toxicological call centres) to establish the safety of treatment by a homeopath and use of over-the-counter homeopathic medicines. A precise definition of ‘homeopathic medicine’ ensured that non-homeopathic cases were excluded. The degree to which a causal link could be established between homeopathic treatment and occurrence of an AE was assessed using the WHO-UMC causality assessment system to allocate cases to one of six clearly defined causality categories: *Certain, Probable/Likely, Possible, Unlikely, Conditional/unclassified, Unassessable/unclassifiable*. Cases of direct AEs from homeopathic treatment were considered separately from cases involving indirect AEs due to failure to use appropriate conventional medical care. Whether the homeopathic treatment given/used was consistent with, or deviated from, ‘standard homeopathic care’ was also considered.

Results: Use of a precise and appropriate methodology resulted in divergent results from those obtained by Posadzki et al. These results will be presented, providing insight into the safety of homeopathic practice and homeopathic medicines.

Keywords: Safety, adverse effects, homeopathy

The translation of prover journals to standard homoeopathic formats: accountability and traceability of proving data

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The conduct of homoeopathic provings has enjoyed a recent resurgence within the homoeopathic community. In more recent years, the pressures to conduct methodologically consistent, scientifically accountable homoeopathic provings within the ICH-GCP framework, the dictates of a number of regulatory authorities and the imperatives of homoeopathic philosophy has lead to the development of a range of proving guidelines.

Notwithstanding these positive developments within homoeopathic proving methodology itself, the accountable and traceable translation of subjective prover journal data to materia medica and reportorial formats remains an area of weakness. The author draws on his experience as a proving supervisor and principal investigator in a large number of provings, and his role in the recent development of proving guideline development, to elaborate a unique method for systematically processing prover journal data through the phases of editing, determination of symptom validity, placebo-verum comparison, materia medica compilation, rubric allocation, reportorial classification and grading, and proving reporting and formatting.

The method is transparent, easy to implement and systematic. The most important characteristics of the method are consistency, traceability of all materia medica entries and rubrics to their prover journal source, and the transparency and relative objectivity of scientific decision-making.

Keywords: Homoeopathic provings; accountability; traceability; materia medica; repertory

Homeopathy and complementary medicine for cancer patients: results of a survey on integrative oncology centres in Europe

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Aims: The principal aim was to map centres across Europe prioritizing those that provide public health services and operating within the national health system in integrative oncology (IO).

Methods: A cross-sectional descriptive survey design was used to collect data. A questionnaire was elaborated concerning integrative oncology therapies to be administered to all the national health system oncology centres or hospitals in each European country. These institutes were identified by convenience sampling, searching on oncology websites and forums.

Results: Information was received from 123 (52.1%) out of the 236 centres contacted until 31, December 2013. Forty-seven out of 99 responding centres meeting inclusion criteria (47.5%) provided integrative oncology treatments, 24 from Italy and 23 from other European countries. The number of patients seen per year was on average 301.2 ± 337 . Among the centres providing these kinds of therapies, 33 (70.2%) use fixed protocols and 35 (74.5%) use systems for the evaluation of results. Thirty-two centres (68.1%) had research in progress or carried out until the deadline of the survey. The CAMs more frequently provided to cancer patients were acupuncture: 26 (55.3%), homeopathy 19 (40.4%), herbal medicine 18 (38.3%), traditional Chinese medicine 17 (36.2%); anthroposophy 10 (21.3%); homotoxicology 6 (12.8%); other therapies 30 (63.8%). Treatments are mainly directed to reduce adverse reactions to chemotherapy (23.9%), in particular nausea and vomiting (13.4%), and leukopenia (5%). The CAMs were also used to reduce pain and fatigue (10.9%), to reduce side effects of iatrogenic menopause (8.8%), to improve anxiety and depression (5.9%), gastrointestinal disorders (5%), sleep disturbances and neuropathy (3.8%).

Conclusions: Mapping of the centres across Europe is an essential step in the process of creating a European network of centres, experts and professionals constantly engaged in the field of integrative oncology, in order to increase the knowledge in this field and provide evidence-based healthcare

Keywords: Integrative oncology centres, European survey, homeopathy

Improving cough treatment with a mixed methods approach

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Homeopathic prescriptions are based on a large amount of clinical experience and proving symptoms. The analysis of these data was hitherto mostly qualitative; we know that some symptoms are a good indication for a specific homeopathic medicine, but we don't know how good. Statistical variance is neglected. Some medicines are prescribed millions of times. For these medicines, every possible symptom will be seen in a cured case eventually by mere chance. This doesn't mean that each symptom is an indication for that medicine. Following Bayes' theorem a symptom is an indication for a medicine, only if the prevalence of the symptom in the population responding well to that medicine is higher than in the remainder of the population. This is expressed as likelihood ratio (LR). Higher LR means a better symptom. This requires quantitative analysis of clinical data in prognosis research.

There are good reasons to optimise homeopathic prescribing for cough; the most frequent indication in general practice with scarce conventional therapeutic options and a frequent reason for prescribing antibiotics. There is some evidence of efficacy of homeopathy for this indication.

Quantitative analysis of some data collections learns that performing quantitative research in homeopathy on existing databases is a challenge. Comparability can be improved. There is confirmation bias, especially in cases with short follow-up. Another problem is how to identify each successful case where the medicine caused the improvement and to skip cases with no real effect. This has great impact on quantitative analysis.

Analysing existing databases on cough shows that coherence and effectiveness can be improved. Quantitative data show that the quality of our knowledge about 'cough medicines' is insufficient, but quantitative analysis is still inconsistent, probably biased and distinction between real cases and spontaneous recovery problematic. With a mixed methods approach we strive for mutual enhancement of both qualitative and quantitative research in homeopathy.

Keywords: Cough, mixed methods research, prognosis research, Bayes' theorem

Clinical trial for evaluation of a HIV Nosode in the treatment of HIV infected participants

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Introduction: Identifying the need for strengthening of immune system, the investigator has developed new HIV nosode and evaluated its effect on HIV positive individuals through a clinical trial.

Method: Standardized and scientific method of HIV nosode preparation has been described and documented. A clinical trial in thirty HIV positive individuals was conducted using the HIV nosode in 30c, 50c potencies. Ethical aspects, safety and inclusion exclusion criteria were taken care of.

Results: Out of twenty-seven participants, 25.93% showed sustained reduction in viral load. 33.33% showed an increase in the CD4+ counts by 20% at either week twelve or twenty-four. Significant weight gain was observed at week twelve ($p = 0.0206$). A significant proportion of participants, 63% and 55% showed overall increase in either appetite or weight at week twelve and twenty-four respectively. The viral load increased from baseline to week twenty-four through week twelve in which the increase was not statistically significant ($p > 0.05$). 37% participants have shown improvement (1.54-48.35%) in CD4+ count and 15% had a stable CD4+ percentage count until week twenty-four. Sixteen out of twenty-seven participants had a decrease (1.8- 46.43 %) in CD8 count. None of the AEs led to discontinuation of study.

Conclusion: The study results revealed improvement in immunological parameters, treatment satisfaction, reported by an increase in weight, relief in symptoms, and an improvement in quality of life, which opens up possibilities for future studies.

Keywords: HIV nodose, HIV infection, CD4, viral load, homeopathy

A group of recent provings in which the new HPCUS Provings. Guidelines were applied: Some comments on the methodology.

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The presentation will give an overview of our experience of 5 provings (pathogenetic trials) which were conducted using the new HPCUS Guidelines (published April 2013). All the provings were randomized double-blind, placebo-controlled and used an unbalanced parallel group design, to establish a homeopathic symptom picture of the substance being proved.

The methodological requirements included:

- IRB approval
- Specific requirements regarding Proving personnel qualifications and training. This included ethics training, especially for the Proving Director.
- Prover insurance
- A placebo group (of 20%)
- Evaluation criteria for assessing the Proving symptoms
- A process for assessing and recording any Adverse Events encountered during a proving.

We will present our experience of applying the guidelines, the end result of which was a group of high-quality scientifically-accountable provings with useful homoeopathic symptom pictures.

Keywords: Provings, pathogenetic trials, HPCUS provings guidelines, placebo-controlled

Single-blind study assessing the individualized homeopathic treatment of cancer patients versus placebo

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Introduction: Aim of our study was to compare the effects, on clinical and quality of life (QoL), of the individualized homeopathic treatment (IHT) versus placebo in patients with advanced cancer, receiving conventional palliative care, since there is no literature in this comparison.

Materials and Methods: Prior authorization, we enrolled 16 patients with advanced cancer admitted to our Emergency Medicine Unit for acute illnesses since april 2014. After resolution of acute conditions through conventional therapies, patients were divided into two groups, matched for age, sex and clinical conditions. Following informed consent, a group was started to IHT, the other to placebo. To assess patients’ physical and mental conditions and their QoL, in addition to clinical-instrumental examination, we used the EORTC-QLQ-C30 questionnaire in basal conditions, after a month and after four months of treatment. Statistical analysis was performed using the Student’s t-test.

Results: The IHT group had significant clinical improvements compared to the control. We achieved significant improvements in laboratory tests only in IHT group. All the patients had, in basal conditions, important clinical problems such as: anxiety, depression, anorexia, phobias, panic attacks, erectile dysfunction, frigidity, important physical disabilities, intolerable pains that did not respond to analgesics; all these conditions were markedly improved only in the IHT group. From the EORTC-QLQ-C30 questionnaires analysis, all patients had a bad perception of their QoL at baseline and encountered many difficulties in daily activities. In the control questionnaires after a month, QoL’s perception improved significantly only after IHT. Even more pronounced the gap between the two groups at four months. Reduced intake of psychotropic drugs in IHT group. No significant side effects were detectable.

Conclusions: The IHT improves the clinical condition and QoL of patients with advanced cancer. The improvement obtained is statistically significant compared to placebo.

Keywords: Advanced Cancer, Homeopathic Medicine, EORTC-QLQ-C30, QoL.

Physicochemical investigations of homeopathic potencies: a systematic review of the literature

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Background: Physicochemical investigations of homeopathic potencies have a long tradition dating back to the end of the 19th century. In order to direct future research, it is necessary to have a solid overview over previously used methods and experimental results. For this systematic review, we focus on laboratory experiments that investigate physicochemical properties of homeopathic potencies.

Methods: Relevant publications were searched for in databases (SCOPUS, Embase, Web of Science, HomBRex, PubMed), article references, and personal collections of literature. Eligible documents were peer-reviewed articles, theses, books, book sections, and conference proceedings without language restrictions. Biological systems (cells, plants, animals), biochemical systems (enzyme activity), and mathematical models were excluded.

All articles found were rated by two reviewers according to a previously developed and adapted Manuscript Information Score (MIS). Articles can score between 0 and 10 points, as 0 to 2 points are given each for description of: experimental procedure, materials, measuring instruments, potentiation method, controls. Articles with an average MIS ≥ 5 are considered of sufficient quality to be retained for further review.

Results: The literature search provided 240 references. We were able to obtain 230 of these publications. After initial scanning of the papers only 155 were found to be investigating homeopathy. Of these, 109 publications had a MIS score ≥ 5 . Among the physical and chemical methods used are: nuclear magnetic resonance (¹H, ¹³C); spectroscopy (UV, VIS, IR, FT-IR, Raman); luminescence, delayed luminescence, thermoluminescence; fluorescence; conductivity; calorimetry; pH; atomic force microscopy, and transmission electron microscopy.

Discussion: More results will be presented at the conference.

Keywords: Physical chemistry, homeopathy, fundamental research, physicochemical methods

Homeopathy in self-reported depression: A pragmatic randomised controlled trial

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Introduction: Depression is a major healthcare problem all around the world. The WHO predicts depression will become the main burden of disease worldwide by 2030. Antidepressants and other conventional treatment may help some patients, although others respond insufficiently or not at all, experience too many side-effects or do not want to use such treatment. Depression is one of the main reasons why patients consult with homeopaths. Existing evidence of the effectiveness of homeopathy in depression is limited.

Aim: To evaluate the acceptability and effectiveness of adjunctive treatment provided by homeopaths for patients with self-reported depression in addition to usual care, compared to usual care alone.

Methodology: A pragmatic randomised controlled trial (RCT) was used to assess the effectiveness of an offer for treatment by homeopaths as an adjunct to usual care. The cohort multiple RCT (cmRCT) design was used and patients were recruited through the Yorkshire Health Study, a UK National Institute for Health Research (NIHR) funded cohort with 27,000 patients. In order to increase external validity, wide selection criteria were used and individualised homeopathic treatment was offered for a 9 month period. Outcome measures included the Patient Health Questionnaire (PHQ-9) and the Generalised Anxiety Disorder (GAD-7) self-reported outcome measures. Results were measured at 6 and 12 months. An intention to treat analysis was carried out to assess the offer for treatment. A complier average causal effect (CACE) analysis was used to assess the effect of treatment received.

Results: A total of 566 patients were eligible to be included in the trial, with 381 patients in the “No offer” group and 185 in the “Offer” group. Out of 185 patients, 74 accepted the offer for treatment and received treatment. Results will be presented.

Keywords: Homeopathy, randomised controlled trial, cohort multiple RCT design, depression, PHQ-9, anxiety, GAD-7, intention to treat (ITT) analysis, complier average causal effect (CACE) analysis

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Poster Presentations

P1

Dr Klaus von Ammon

Fri 5 June, 17.00

Use of homeopathy in patients with organ transplant in Switzerland: first results and further steps

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Objective: To investigate retrospectively use of Complementary and Alternative medicine (CAM), in particular homeopathy, in the treatment of patients with organ transplantation in Switzerland and to present a roadmap to follow-up.

Methods: Members of the Swiss transplant association were asked to complete a questionnaire about CAM use retrospectively.

Results: Of the 267 patients contacted, 124 (46%) completed the questionnaire, and data of 118 (44%) participants could be analyzed: 55 were women (47%), mean age was 56 years, and 64 (54%) indicated CAM use.

Different CAM methods were most common, with classical homeopathy being the most popular during the underlying disease leading to transplant (15% of all participants), but losing importance before, during and after the transplantation itself. About 25% CAM users had informed their treating physicians about CAM use. Family doctors were mostly supportive, while specialists were more cautious about CAM use. Among the 54 non-CAM users, the most frequent reasons for not choosing CAM were insecurity about interactions with conventional treatment (46%), and lack of information about this option (28%).

Conclusion: The results point to the need of more information on possibilities and limits of CAM as add-on in the treatment of patients with transplantations for both, treating doctors and concerned patients. This could be achieved with mixed methods research: qualitative studies to gain knowledge about the attitude and needs of patients and physicians; clinical studies on the effectiveness and safety of CAM for transplant patients based on the present results.

The effect of disclosing information about prescribed homeopathic medicine to patients on their clinical outcomes: a comparative study

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Background: Dispensing homeopathic medicines in a homeopathic office setting is very common among homeopaths. However, some homeopaths feel uncertain about how and what to disclose to patients about the prescription. Based on findings of our previous study most of the homeopaths do not openly communicate the prescription details because they are concerned about possible negative impact of patient's knowledge of homeopathic medicine on the treatment outcomes.

Objectives: Our study aims at finding evidence about negative or positive effects of the current dispensing methods among homeopaths in Canada.

Methods: A comparative study was performed. The study groups consisted of the patients who had received basic information about their medicines and those who had not. Information on actual practice of prescription, dispensing methods and related patient's reactions, and the treatment outcomes was recorded during the course of treatment, and compared between the two study groups.

Results: Based on the results of our study, there was no statistically significant difference between the patients who received a labeled homeopathic medicine and those who did not in terms of expected treatment effects. Our findings showed that a high proportion of patients receiving a non-labeled remedy who asked about their medicine's name became more anxious and concerned about taking the prescribed medicine when the homeopath refused to provide the requested information.

Conclusion: In our study the negative effects of not labeling homeopathic medicines on treatment outcomes dominated its positive effects. It seems to be essential to develop regulations and standards for prescriptions or office-based dispensing of homeopathic medicines, and to include these standards in training of homeopaths.

Homeopathy in a clinical setting of Integrated Medicine for inpatients in an Italian public hospital. Report of four years of activity

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The Centre for Integrated Medicine of Pitigliano, Tuscany region, was founded in 2011 in order to provide assistance and to carry out scientific research projects to measure usefulness of homeopathy.

In four years of activity we have measured outcomes to evaluate the importance and usefulness of conventional therapies integrated with homeopathy to treat inpatients and outpatients.

In particular:

- the difficulty to join an innovative setting of Integrated Medicine by the medical and nursing staff on duty
- the level of acceptance and appreciation from the inpatients
- the features of the outpatients who are visited in integrated care
- the benefits of integrated cares in the clinical conditions of the inpatients

Results: The project is still in progress despite the initial partial contrariety of some doctors in the hospital and some external family doctors in the area. The positive experience was confirmed by the high approval gained from many health personnel and hospital patients. The measured outcomes are extremely positive, with a great improvement on QoL and they will be illustrated in details.

Effectiveness of the concomitant use of psychotropic pharmaceuticals and individualized homeopathic treatment: A Delphi study

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Introduction: The use of psychotropic pharmaceuticals such as anti-depressants, anxiolytics, anti-psychotics and stimulants has greatly increased in the past two decades. Every homeopath who sees patients with psychiatric diagnoses encounters many patients on these types of medications. The effectiveness of the concomitant use of pharmaceuticals and homeopathic remedies is an issue frequently asked about by patients. Although published individual case reports exist, the question has not yet been addressed in any depth in the published literature. There is currently no consensus or body of research addressing whether individualized homeopathic treatment is equally effective for patients concurrently taking psychotropic pharmaceuticals as for those taking none.

Aim: The primary aim of this study is to investigate the experience and opinion of homeopathic experts as to whether the use of individualized homeopathic treatment by patients also taking psychotropic medications is effective.

Method: Expert homeopaths with extensive experience were invited to participate in a discussion process known as a Delphi study. Delphi is a structured communication method for soliciting expert opinion about complex problems through the use of questionnaires and controlled feedback. The aim of a Delphi study is to develop expert consensus around an emerging subject about which there is controversy or insufficient information.

Results: 8 homeopaths participated in two rounds of questionnaires leading to the development of consensus statements. Statements were generated regarding the effectiveness of homeopathic treatment used simultaneously with psychotropic pharmaceuticals; specific posology adjustments required; and the effectiveness of individualized homeopathic treatment for weaning down on psychotropic medications.

Conclusion: It is the opinion of this panel that individualized homeopathic treatment can be clinically effective for patients concurrently taking or weaning down on psychotropic medication. Pharmaceutical use provides challenges to case analysis and posology choice, but there is a wealth of expert case management experience that has yet to be systematically explored.

Keywords: Individualized homeopathic treatment, psychotropic pharmaceuticals, Delphi, psychiatry

Retrospective observational study of people with HIV and AIDS receiving homeopathic treatment in Swaziland

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The purpose of this ongoing research is to investigate the effectiveness of homeopathic treatment delivered to HIV-positive patients mainly in resource-limited settings. The study includes patients on Antiretroviral Therapy (ART) and those not yet initiated on ART, in Swaziland. Data from the Swaziland Homeopathy Project, 2014 clinic database was analysed.

The study is a retrospective observational study of a group of 1003 HIV positive individuals comprising 147 males and 856 females. Patients attend clinics voluntarily and are offered homeopathic treatment as a complement to any other conventional medical treatment. Statistical analysis was carried out using the Standard Student t-test. The end points are changes in the Practitioner and Patient overall scores (based on Karnofsky) and Symptom Evaluation Scale (VAS) scores.

The analysis showed statistically significant positive changes in all average overall health scores of the patients between initial case-taking prior to remedy prescription and follow-up consultations. Mean patient scores for patients on ART increased by 1.18 points (from 6.11 to 7.29) on the 9-point Karnofsky scale (p value < 0.01). Mean patient scores for those not on ART increased by 0.94 points, from 6.30 to 7.24 (p value < 0.01). Practitioner scores showed similar increases. From all the overall health scores, an average of 66% of the patients showed improvement at the first monthly follow-up. Analysis of the symptoms indicated that symptom improvement occurred in 65% of all presenting symptoms at first follow-up. This trend was observed for both mental and physical symptoms.

The study indicates that all patients, including those receiving ART and those not yet initiated, were significantly improved after receiving homeopathic treatment. Symptom analysis indicates that homeopathic treatment can alleviate both long and short-term ART adverse effects including peripheral neuropathy and is effective in addressing emotional issues such as grief and trauma as well as opportunistic infections.

Keywords: Outreach homeopathic treatment, observational study, HIV-positive patients, Antiretroviral Therapy (ART), overall scores, symptom scores, statistically significant improvement

Study design of a Randomized, Placebo Controlled Trial of the Homeopathic Treatment of Attention Deficit Hyperactivity Disorder (ADHD)

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Background: ADHD is a common psychiatric disorder affecting 5-10% of children and youth. Conventional treatments for ADHD are effective in treating acute symptoms but have shown little long term benefit and have a troublesome adverse event profile. Homeopathic treatments for ADHD have shown promise however the therapeutic effects are unknown. Homeopathic randomized, placebo controlled trial (RPCT) are difficult to design. The homeopathic research community has conducted many such RPCT's and valuable lessons have been learned.

Methods: Our study team has designed a study of the homeopathic treatment of ADHD which we feel may address more rigorously the questions around internal, external and model validity in homeopathic trials. We have designed a 3 arm (verum, placebo, waitlist) RPCT after conducting an open label pilot study. The pilot study enabled the study team to determine feasibility, optimal length of time needed for treatment, and to make a sample size calculation on the treatment-waitlist arms. The current study has a treatment phase of 28 weeks (8 consultations) and intends to enroll 59 participants per arm. One key element of the design of the study was to retain the same clinicians for both the pilot phase and the RCT phase so that the sample size calculation may more accurately reflect a particular standard of practice. Furthermore, the practitioners were chosen based (in part) by their lack of reputation and popularity in the community. This has the potential to reduce certain biases (such as reputational, popularity, and hot stuff biases) allowing for the potential of more robust results. To optimize model validity both the pilot study and the RPCT had continuous input from the homeopaths with regards to emulating their standard practice with the clinical aspects of the trial. Very few modifications were introduced and the homeopaths did not feel that these modifications would affect patient outcomes.

Keywords: Homeopathy, ADHD, Attention Deficit Hyperactivity Disorder

Effectiveness of homeopathic remedies in severe laminitic horses

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Background: Equine laminitis is a severe inflammation of the internal lamellar of the horse foot due to an alteration of the periferic vascular flood flow. Marked vascular disturbances occur and microtrombi form in the digital vasculature, which is primed for neutrophil invasion and activation. Endotoxin exarcebate endothelial cell dysfunction, increasing endothelin-I and reducing Endothelial Nitrix Oxide Synthase (eNOS) activity. Ischaemic and inflammatory stimuli could also activate MMPs, leading to digital failure: destruction of the basement membrane bonding the interlocking lamellar leaflets, leads to detachment of phalanx bone from the hoof wall. Ischemia (I) triggers an inflammatory response that precipitates cell death during reperfusion (R).

Nitric Oxide (NO) is an inflammatory mediator produced by macrophages and neutrophils during the inflammatory response. It is synthetisized via oxidation of L-Arginina by Nitrix Oxide Sinthases and plays an ambiguous role during I/R. Additionally, NO mediates the activation of Soluble Guanylyl Cyclasa, which can also be activated by endogenous Carbon Monoxide (CO). Metabolism of heme and lipid peroxidation, which generate CO, are both enhanced during inflammation.

Methods: 5 horses (4 mares and 1 stallion) diagnosed with acute severe laminitis were treated with homeopathic remedies; 10 healthy horses were selected to determine whether homeopathic remedies are useful and safe as a treatment for equine laminitis, if the level of NO can be re-established and the role of CO. Laminitic horses were administered oral homeopathic treatment only: Aconitum 30ch, Apis 15ch, Arnica 7ch, Belladonna 9ch, Bryonia 9ch and Nux vomica 9ch – 2 granules of each remedy every hour, 10 times per day for 10 days. Variables evaluated included signs of pain, grade of lameness, digital pulse, NO, Nitric Oxide Synthases Expression, CO and Hemeoxigenases Expression in plasma levels.

Results: Homeopathy-treated horses showed an obvious improvement after one day of treatment. Clinical signs of the disease (pain, severe lameness) had completely disappeared at the third day without side effects. NO diminished in laminitis has significant recovery levels in mares. CO and HO-1 levels were higher than in healthy horses.

Keywords: Horses, ischemia, laminitis

Literature Review of the In Vitro and In Vivo Evidence for Homeopathic Medicines in the Treatment or Prevention of Malaria

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Background: Malaria is a vector borne infectious disease that affects over 200 million people worldwide every year. Access to treatments on a large-scale is challenging due to the vast geographical and rural spread. Homeopaths have treated infectious disease throughout its 200+ year history however robust data on the efficacy and effectiveness of homeopathic treatments for malaria are lacking.

Objectives: To explore the research that has been conducted regarding the use of homeopathy for malaria.

Methods: A literature search was performed on the following databases: EBSCO, CINAHL Plus with Full Text, Humanities International Complete Medline with Full Text, Social Sciences Abstracts (H.W. Wilson) and Google Scholar. The search terms used were: “malaria and homeopathy” and “plasmodium and homeopathy”. Articles were deemed ‘relevant’ if the article discussed homeopathy in relation to malaria or anti-malarial properties, and/or if they indicated treatment decisions.

Results: Three studies were deemed relevant in this search. Rajan and Bagai studied an in vitro culture, Bagai, Rajan, and Kaur explored an in vivo test and the State Health Resource Centre in Chhattisgarh explored the distribution of a homeopathic intervention to almost 100,000 people.

Conclusions: There is minimal data examining homeopathic treatments in the treatment and prevention of malaria. The few studies have shown some interesting findings and further research is needed to discern details such as an ideal choice of potency and ideal amount of remedy repetition for optimal results in this population.

Keywords: Homeopathy, homeoprophylaxis, malaria, Plasmodium, anti-malarial, China, China sulph

Rationale for a pragmatic randomised controlled trial of the effectiveness of treatment by homeopaths for ADHD

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Objective: To design a trial with minimal potential for bias (maximal internal validity) representing treatment by homeopaths as experienced in routine clinical practice (maximal external validity) informing ADHD stakeholders such as families and decision makers in health, education, social work and criminality.

Methods: Recruitment of a long term observational cohort of children with ADHD. Measurement of subjective outcomes (parent measurement of core ADHD symptoms, anger and wellbeing); blinded outcomes (teacher rated core ADHD symptoms, classroom disruption); and objective outcomes (criminality, school exclusion, attendance, and costs). A random selection of cohort participants meeting trial criteria is offered treatment by homeopaths or essential fatty acids. Those meeting trial criteria not randomly selected act as a 'treatment as usual' control group. Primary analysis compares the clinical and cost effectiveness of each intervention with treatment as usual.

Results: Internal validity. Comparing more than one intervention ensures that biases associated with unblinded studies (e.g Hawthorne effects) are equally distributed across groups. Unblinded parent reported outcomes are at risk of expectation biases. Measurement of blinded outcomes by teachers, and objective outcomes such as levels of criminality, resource use, school exclusion and attendance, minimises the risk of biased outcome assessment. External validity. The design assesses the real world effectiveness of the total package of care (provision of individualised homeopathic remedies, freedom to change remedies and potency, and regular consultations). It assesses the therapeutic potential of the intervention; it measures objective outcomes of interest and cost effectiveness which provides useful information for stakeholders; and it addresses treatment bias towards interventions suitable for blinded studies.

Conclusion: Previous trials have assessed the efficacy of homeopathic remedies and probably underestimate effects due to the interacting nature of components. Complex therapies such as homeopathy are best measured in their totality but potential for bias must be addressed

Keywords: ADHD, homeopathy, pragmatic trial design, complex intervention

Homeopathic treatment for otitis media in children: the case for pragmatic trialsAlison Fixsen

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Otitis media with effusion (OME) or ‘glue ear’ is the most common cause of pediatric hearing loss, and a drain on global health care resources. Socio-economic and environmental factors play a significant part in severity and impact of OME on cognitive and developmental outcomes. Development of otitis media associated with frequent episodes of acute otitis media and respiratory tract infections (RTIs) and linked with environmental and social factors, including diet, parental smoking, overcrowding and day care use. The unsatisfactory nature of current conventional treatment strategy for OME, in particular growing concerns about excessive or inappropriate antibiotic use, signifies an ‘effective gap’ (Fisher et al, 2005) in pediatric medicine. Homeopathy is a relatively common choice of CAM treatment for childhood conditions, including otitis media. With antibiotic resistance now a global problem, homeopathy could have a role to play in combating its further development (Viksveen, 2003). A number of randomized trials and outcome studies using homeopathy for acute otitis media and upper respiratory tract disorders have been conducted, encouraging results. Literature searches indicated a scarcity of homeopathic clinical research into OME (Fixsen, 2013), with only one clinical trial devoted to its use (Harrison, Fixsen and Vickers, 1998). In this presentation I consider the social and cultural implications of OME, and its impact on high-risk individuals and communities. I use case studies to illustrate the complex nature of the problem, including evaluation of safety and efficacy of present treatment strategies. Finally I consider the use of small-scale internationally based homeopathy trials of OME, using a pragmatic framework and evaluating long term effects of homeopathic treatment in different settings, in conjunction with other healthcare and social services, including nutrition and lifestyle education, in an integrative approach to public health.

How to deal with missing data in the analysis of a quality of life study in cancer patients with randomized adjunctive classical homeopathy

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The aim of this study was to evaluate whether homeopathy had an influence on global health status and subjective wellbeing when used as an adjunct to conventional cancer therapy.

In this pragmatic randomized controlled trial, 410 patients, who were treated by standard anti-neoplastic therapy, were randomized to receive or not to receive classical homeopathic adjunctive therapy in addition to standard therapy. The study took place at the Medical University Vienna, Department of Medicine I, Clinical Division of Oncology. The main outcome measures were global health status and subjective wellbeing as assessed by the patients. At each of three visits (one baseline, two follow-up visits), patients filled in two different standard questionnaires.

As expected, the study had to deal with a considerable amount of missing values for the outcome measures. After informed consent and randomization, 37 patients (16 in the homeopathy group, 21 in the control group) declined to further participate, leaving 373 patients with baseline measures. 335 patients completed at least two scheduled visits, 282 measurements were available for the third visit. The improvement of global health status and subjective wellbeing between visit 1 and 3 was significantly stronger in the homeopathy group when compared to the control group.

In the statistical analysis missing values were taken into account by using the multiple imputation technique. This method and its underlying assumptions (missing at random) will be explained and discussed. Furthermore, sensitivity analyses under various alternative assumptions concerning the missingness mechanism (missing not at random) will be presented to evaluate the dependence of the results in the primary analysis on these assumptions. The positive results for subjective wellbeing turned out to be robust even in extreme scenarios of deterioration in homeopathy patients with missing values. This study demonstrates that modern statistical methods are able to adequately deal with missing data.

Keywords: Oncology, classical homeopathy, quality of life, subjective wellbeing, missing data

Learning Technologies in Homeopathic Medicine Education: Drilling deeper into the dynamics and changing behaviours of the student body in complementary and homeopathic medicine.

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Background: There are emerging trends in learner attitudes, behaviour and values in relation to technology and learning within the complementary medicine field. No longer do colleges such as Endeavour College have a simple, homogenous student body. Now significant diversities in age, demographic and psychographic are increasingly present. In the last 3 to 5 years new features have emerged, with 'wellness sector', forward looking, proactive learners arriving in the classroom.

Method: A survey is undertaken annually in which all current students at Endeavour College were invited to participate. The Student Technology Survey examined the personal and educational use of technology, confidence and fluency in working with technology as a student, and attitudes and perceptions of technology and other facilities within the college. This paper drills into this survey data and reports on the interim results of three years of the homeopathy student voice at a large multi modality college of CAM.

Results: Responses to the survey over 3 years varied (Year 1 – n=508; Year 2 – n=572; Year 3 – n=576). Rapid rise in the use of tablets (57%) in learning dominates the results and changing behaviours, and the increasing use of social media channels to facilitate student learning communities and accessing study resources. Increasingly, learners (39%) use the learning management system daily.

Discussion/Conclusion: Front and centre of this yearly collation of students attitudes and decisions is the growing use and in fact dependence on technologies, from apps, to learning management systems, on hardware such as smart phones and tablets. The data points to supporting the clear trends in the university sector world wide, but also key differences, with some resistances to the use of technologies, due to the unique values, demographics and psychographics of those who attends the college, and highlights urgent infrastructure priorities for CAM education.

Homoeopathic approach towards the treatment of advanced cases of thromboangitis obliterans

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Background: A study involving 70 cases of thromboangitis obliterans was done over a 10-year period. Each case was closely monitored for 10 years even after completion of treatment. Thromboangiitis obliterans (also known as Buerger's disease) is a recurring progressive inflammation and thrombosis of small and medium arteries and veins of the hands and feet. It is strongly associated with use of tobacco products, primarily from smoking, but also from smokeless tobacco. The main symptom is pain in the affected areas, at rest and while walking (claudication).

Procedure: Cases were recorded in exhaustive detail: distinguishing symptoms, past history, family history, modalities, likings, physical generals, laboratory investigations and angiogram studies. After careful analysis and thorough repertorisation, a similimum was chosen and the homoeopathic remedy was administered according to the individual case. The case was followed up thoroughly after a month and action was taken accordingly. An angiogram was done to assess the condition of the arteries and after one year of treatment again the procedure was repeated till the patient was healed completely.

Results: The study proved the efficacy of homoeopathic treatment. Out of 70 cases chosen, 63 cases were completely cured; 4 cases had tremendous improvement in their condition and 3 cases were discontinued shortly after starting treatment. There was recurrence of the problem in 7 cases where the patients started smoking again after treatment. Out of 15 cases where amputation had already taken place, 14 were completely cured after treatment.

Conclusion: In advanced cases of Thromboangiitis obliterans homoeopathic medicines have proved highly successful in providing miraculous cure to the immensely suffering patients. Homeopathic treatment was equally effective in cases where amputation had already taken place.

Keywords: Thromboangiitis obliterans, claudication, angiogram

An evidence based study of homoeopathic treatment and its effectiveness in the treatment of adnexal cysts and breast lumps: An exhaustive study

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Background: A study of 100 cases (63 breast lumps and 37 ovarian cysts) was undertaken to study the efficacy of homoeopathic medicines in these cases. All cases were divided into 3 categories based on their size: A (big – 5 cm and over), B (medium – 3-5cm) and C (small – 0-3 cm). A sonomammogram of the breast was done before and after treatment in all cases, to provide scientific evidence of the study.

Method: Each and every case was studied thoroughly and classified according to the size of cyst and after complete repertorisation a specific remedy was chosen for a particular case and was administered accordingly. Follow up was done after every fifteen days. Sonomammograms were done in each and every case before and after treatment to confirm the exact size and condition of the patient.

Results: In 31 cases the ovarian cysts completely dissolved. In 4 cases there was significant reduction in the size of cysts, but not complete dissolution, and in 2 cases there was no change in the size of the cyst. In 51 cases of breast lumps, the lumps were dissolved completely, while in 6 cases there was significant reduction in the size of cysts, and in 6 cases no change was seen. Out of 31 completely cured cases of ovarian cysts, 17 cases belonged to category C (size 0-3 cm), 10 cases of category B (3-5 cm size) and 4 cases of category A (5 cm and over). The maximum size that was cured completely was 5.7 x 5.1 cm in size. In cases of breast lumps, out of 51 cured cases, 6 cases belonging to category A, 14 cases to category B and 31 cases to category C, were completely cured.

Conclusion: Constitutional treatment proved to be highly effective in the treatment of adnexal cysts and breast lumps.

Keywords: Adnexal cysts, sonomammograms, constitutional treatment

Ultra-high dilutions of homeopathic remedies alter cell viability and induce apoptosis in the MCF-7 human-cancer-cell-line in an in vitro environment

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Homeopathy is a CAM therapy widely used around the world to treat diseases, cancer being one of them. This trial addresses the question if cancer cells could directly be affected by homeopathic preparations. I used an in vitro setup with automatized screening for cell viability and apoptosis for this purpose. Ultra high dilutions (C30, C200) prepared according to the homeopathic pharmacopeia and therefore called potencies of different remedies (Phosphorus, Carcinosisin, Phytolacca, Thuja, Asterias, Carbo animalis, Agaricus phalloides, Sabal serrulata) had been tested on cultures from breastcancer cell line MCF-7. HEK293 served as control for cell specificity. The potencies had been tested against demineralized water and dilutions of unpotentized saccharose. Remedies were applied in an 11 point two fold series of dilutions in duplicate. This trial showed that Phytolacca and Carcinosisin altered the viability of MCF-7, whereas the HEK-cells showed only little response. There was no clear correlation between the viability test and the apoptosis test after 24h, thus the main effects on viability occurred either due to cell cycle delay or arrest. Phytolacca and Carcinosisin showed a distinct pattern of activation and inhibition over the series of dilutions that was very different from other remedies and controls. Strikingly the same dilution could increase or decrease the viability. The findings suggest that ultra-high dilutions of substances have biological activity apart from placebo effects. Remedies that are used since decades to treat breast cancer and are currently used in the Banerji-Protocols showed their ability to significantly alter the behavior of cancer cells through changes in viability and induction of apoptosis.

Keywords: Cancer, in vitro, viability, apoptosis, MCF-7, ultra-high dilution, cell lines, Phytolacca, Carcinosisin

Cytokine production in mice perinatal model treated by LPS and Zincum metallicum

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Background: This preliminary study developed a model of LPS-induced stress for evaluation of inflammatory process in F1 generation after mother's treatment with Zincum metallicum (Zm).

Object: To evaluate the cytokine production in vivo in mothers and in F1 generation with the possible effect of homeopathic dilution of Zincum metallicum.

Methods: Animal ethics CEUA-UNIP#156/13. 26 BALB/c parental females (Pf) were divided in 8 groups. LPS (n=19) and no-LPS (n=7) each with subgroups: no-Zm, Zm-200cH, Zm-30cH, Zm-5cH. LPS treatment: 9.5 day of Pf pregnancy; and all F1 24h before euthanasia. Peritoneal washes collected after Pf weaning recovery; and F1-adulthood. The cytokines CCL2, IL-6, IL-10, TNF-alpha, IL-1-beta; IL-12 were ELISA assayed; Nitrite+nitrate by Griess reaction.

Results: In Pf LPS decreased cytokines production especially CCL2, in non-statistically significant way due to high variability and low sample size. This trend was reproduced also in F1 of the same mothers. Zm high dilutions showed a trend to counteract this effect. A marked significant difference in LPS-induced CCL2 and IL-10 production was observed between F1-males (high) and F1-females (low). Zm-200cH and Zm-30cH treatment of mothers increased the CCL2 and IL-10 production in F1-females in a non-statistically significant way. Nitrite+nitrate in Pf was affected by the Zm treatment ($p < 0.01$), with the maximum effect seen with the Zm-200cH, without influence from the LPS treatment. In F1 generation the Nitrite+nitrate was double in females than in males but no differences were observed between groups for Zm treatment of mothers.

Conclusions: This exploratory study does not rule out the possibility that Zm affects the inflammatory responses in mothers and F1, but further studies with higher number of animals per group would be necessary to reach definite conclusion. The gender markedly affected the F1-cytokine response. CCL2 could be considered one of the best indicators of the in vivo response to intraperitoneal LPS.

Keywords: BALB/c mice, perinatal, cytokines, LPS, ultra-high dilution, Zincum metallicum

Homeopathy for marine fish aquaculture: Increased growth and survival of juvenile spotted rose snapper *Lutjanus guttatus*

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Homeopathy medicines have been applied with positive results in agriculture, livestock and freshwater aquaculture. Commercial formulations such as Homeopátula™ have been successfully evaluated in Nile tilapia (*Oreochromis niloticus*) and Pacu (*Piaractus mesopotamicus*) with measurable effects on growth, survival, and immune response during culture, management and transport. The spotted rose snapper *Lutjanus guttatus* is a marine fish with meat of exceptional quality, and commercial importance because of its potential for marine aquaculture.

To assess the value of homeopathy on health enhancement of the species, ten groups of 30 juveniles each (8.72 ± 4.07 g; 8.47 ± 1.24 cm) were cultivated for 30 days in 120 L fiberglass cylinders provided with continuous aeration and filtered ($50 \mu\text{m}$) seawater daily exchanged by 900%. An experimental design with five different treatments, each one with two replicates, was developed to determine the effect of three homeopathic mixes: Hel-Mix, Pav-Mix, and Hel-Mix/Pav-Mix, and two control groups: No-Medication (NM) and Ethanol 30°GL (E). Homeopathic medicines (31CH) in treated groups and E in control group were sprayed (5% V/W) in commercial balanced food (Silvercup™) and supplied ad-libitum five times a day. Growth in total length and live weight was expressed as percentage increase.

A significant ($p < 0.05$) increase ($T_1 - T_0$) in total length and live weight occurred with homeopathic treatments Hel-Mix/Pav-Mix (15.17% and 68.16%), Pav-Mix (11.50% and 55.04%) and Hel-Mix (9.88% and 47.83%). No significant ($p < 0.05$) increase ($T_1 - T_0$) occurred with control treatments NM (5.39% and 13.97%) and E (0.11% and 5.40%). Significantly ($p < 0.05$) higher survival (93.1%) occurred in homeopathic treatments Pav-Mix and Hel-Mix, compared to homeopathic mix Hel-Mix/Pav-Mix (50%) and both control groups (48.21%).

These results suggest that homeopathic medicines have potential application in marine fish aquaculture. We recommend studying overall response of broodstock, larvae and juveniles treated with homeopathic medicines to improve hatchery operations from spawning to stocking size

Keywords: Aquaculture and homeopathy, fish growth and mortality

Homeopathy for mollusk aquaculture: Increased growth, survival, and protection of juvenile Catarina scallop *Argopecten ventricosus* against bacterial pathogen-challenge

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Mortality by vibriosis in pectinids such as “Catarina” scallop *Argopecten ventricosus* is mainly caused by the pathogen bacteria *Vibrio alginolyticus*. The use of increasingly potent antibiotics generates bacterial resistance, so new alternatives are required to attain more efficient and eco-sustainable production practices.

A growth bioassay to evaluate the effect of homeopathy in juvenile *A. ventricosus* was conducted for 21 days, and a challenge against *V. alginolyticus* (CAIM 57 www.ciad.mx/caim) was conducted for 120h to evaluate survival post-infection. For the growth bioassay two homeopathic formulas (Pav-Mix/Pha; Pav-Mix/Sit), two antibiotics (Ampicillin; Oxytetracycline) and two controls (No Treatment=NT; Ethanol 30°G=E) were included. Specific controls (NCH-Control= untreated/not challenged and CH-Control= untreated/challenged) were used for the challenge. For growth assessment, juvenile scallops (4.14 ± 0.06 mm, 13.33 ± 0.01 mg) were cultured in 4L experimental units provided with aerated, filtered, and UV-sterilized seawater and a blend of cultured microalgae as natural food. Homeopathic drugs, antibiotics and ethanol were added to the culture water. For survival assessment during the challenge bioassay, experimental units (500 mL) were inoculated with 1×10^7 CFU/mL (LD_{50}) of *V. alginolyticus*. Juveniles grew significantly ($p < 0.05$) larger in weight and height with Pav-Mix/Sit (6.99 ± 0.09 mm; 0.132 mm d⁻¹; 41.16 ± 0.35 mg; 1.35 mg d⁻¹), compared to the control group NT (5.05 ± 0.10 mm; 0.043 mm d⁻¹; 24.33 ± 0.1 mg; 0.54 mg d⁻¹).

Higher post-infection survival rate occurred with Pav-Mix/Pha (85%), compared to Oxytetracycline (30%), Ampicillin (53%) and control group CH (0%). Superoxide dismutase (SOD; % of inhibition; SIGMA 19160 Kit) was especially higher ($p < 0.05$) for Pav-Mix/Pha, in relation to other treatments and controls. Under this experimental evidence, we conclude that homeopathic drugs really improved growth, survival, and immune response in juvenile scallop *A. ventricosus*. The homeopathic drugs could be a potential alternative to antibiotics in mollusk spat hatcheries, and additional benefits could be expected to reduce the progressive increase in bacterial pathogenicity associated to the use and abuse of antibiotics.

Keywords: Aquaculture and homeopathy, mollusk disease and immunity

Homeopathy for shrimp aquaculture: Increased survival and superoxide dismutase activity in juvenile white shrimp *Litopenaeus vannamei* during a bacterial pathogen-challenge

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Homeopathy is a discipline of medical science with successful application in humans, but its effects on growth, survival, immune response, and gene expression of species of plants and animals is still preliminary. We evaluated homeopathy in marine aquaculture of white shrimp *Litopenaeus vannamei* looking for an increase in resistance of shrimp to the pathogenic bacteria *Vibrio parahaemolyticus*, which is associated with acute hepatopancreatitis and early mortality syndrome (EMS) that causes huge economic losses in commercial shrimp farms worldwide.

Juvenile shrimp (8g mean fresh weight) were cultivated with three homeopathic treatments for a four days period (Hel-Mix; Pav-Mix; Vid-Mix; Hel-Mix/Pav-Mix) and then challenged for 120 h against a pathogenic strain of *V. parahaemolyticus* (CAIM 170; www.ciad.mx/caim). The experimental design included two controls (NCH-Control untreated/not challenged; CH-Control untreated/challenged). Homeopathic medicines (31CH) sprayed in commercial balanced food (PIASA™; 35% protein) were provided ad libitum during both culture and challenge periods. Control groups received balanced food without homeopathy. As no mortality occurred with a first dose of 1×10^6 CFU/ml (=LD₅₀) of pathogen strain at the beginning of the challenge, a second dose was added 24 hours later.

96 hours after challenge, superoxide dismutase (SOD, percentage of inhibition) was 44.49% (Hel-Mix), 26.53% (Pav-Mix), 94.30% (Vid-Mix), 91.59% (Hel-Mix/Pav-Mix) and 41.63% (CH-Control) ($p < 0.05$). 120 hour after challenge, cumulative survival was 0% (Hel-Mix), 33.3% (Pav-Mix), 58.3% (Vid-Mix), 50% (Hel-Mix/Pav-Mix), 100% (NCH-Control) and 0% (CH-Control). Hel-Mix/Pav-Mix and Vid-Mix increased survival and immune response in shrimp subjected to stressful conditions associated with *V. parahaemolyticus*, similarly to what happens in infected farms. It suggests that homeopathy has a great potential for application in shrimp aquaculture. Nevertheless, more studies are required to demonstrate that homeopathy can improve the eco-sustainability of aquaculture industry, by increasing health of cultured shrimp and the safety/inocuity of harvested shrimp for human consumption.

Keywords: Aquaculture and homeopathy, shrimp disease and immunity

Differential dose-dependent effects of arsenic in pro- and anti-inflammatory cytokines

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Introduction: Arsenic is known to exert detrimental effects at high doses, due to its action on multiple cellular pathways and epigenetics. Conversely, arsenic-containing agents have been in medicinal use and *Arsenicum album* is widely used homeopathic drug. Lymphocytes, monocytes/macrophages are major targets of *Arsenicum album* and homeopathic Materia Medica associates it also to inflammation and blood alterations. Inorganic arsenic (NaAsO_2 , iAs) has reported multifaceted actions at cell level, that depend on the doses, the time and the type of cells.

Methods: In this study the effect of iAs on human monocytic leukemia cell line THP-1 was analyzed. Dose response experiments have been conducted using iAs concentrations from 10^{-10} Mol/L to 5×10^{-3} Mol/L for 24h with THP-1, cells differentiated into activated macrophages by phorbol (PMA) exposure and primed with the endotoxin LPS (10 ng/ml). Proinflammatory (TNF- α and IL-1 β) and anti-inflammatory (IL-10) cytokines expression was monitored, while variation of viability and cell density were examined by WST assay.

Results: THP-1 cell metabolic activity dropped to 20% of the control after 24h exposure to 10^{-4} Mol/L iAs, while lower concentrations did not affect the viability. Cell survival was not improved after pre-sensitization of the cells for short times (2-3h) with sub lethal doses of iAs. Pro-inflammatory cytokines IL-1 β and TNF- α showed hormetic-like dose-response with peaks around 10^{-6} to 10^{-5} Mol/L iAs, while the anti-inflammatory cytokine IL-10 was downregulated by iAs in dose-dependent fashion. These results suggest different signal pathways engaged by arsenic in macrophage cells. Little effects of *Arsenicum album* high dilutions were found in the THP-1 cellular model explored so far. Further results will come from the analysis of other biomarkers involved in inflammation and stress response signaling under *Arsenicum album* conditioning in THP-1 and other primary immune cells.

Keywords: *Arsenicum album*, macrophages, cytokines

The patient's 'journey to cure' as a quantum theoretically-based topological metaphor

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Introduction: A metaphor for the therapeutic process was previously developed based on the discourse of novel generalised forms of quantum theory, from which the constraints of Planck's constant have been removed. This metaphor combined three-way quantum-like 'entanglement' between patient, practitioner, and the remedy/therapeutic modality with a representation of the patient's Vital Force (Vf) as a quantised spinning gyroscope. This led to a semiotic quantum/topological metaphor for the patient's 'journey to cure'. Two new models for the homeopathic therapeutic encounter are proposed, based on a) a quantum-mechanical model of Adaptive Mutation (QMMAM), and b) geometric patterns generated by a light source attached to a spinning gyroscope.

Method: a) QMMAM suggests superposition of DNA with mutant adaptations. Environmental pressure then 'collapses' the DNA wave function to a favourable state. Using QMMAM as a *metaphor* for the therapeutic process, isolation-induced coherence between patient, practitioner, and remedy, may be thought to generate a quantum-like 'superposition' of patient 'unwell' and 'well' states. b) Light beams attached to precessing gyroscopes sweep out ellipses that become circular the faster the gyroscopes spin, and the less they precess. Ellipses have two foci that, again as a *metaphor* for the state of a patient's Vf, are seen to represent the patient's 'unwell' and 'well' states. The faster the Vf gyroscope spins, the more these foci merge.

Results: a) In the QMMAM metaphor, a patient's superposed 'unwell' and 'well' states may 'collapse' to the cured state, following decoherence at the end of therapeutic process. Similarly, b) the curative therapeutic process may be thought to 'spin up' the patient's Vf, so the precessing ellipse's 'foci' (i.e., 'unwell' and 'well' states) merge into a 'circular' cured state.

Conclusion: These new models may be seen as equivalent, semiotic simplifications of a previous quantum/topological description of the patient's 'journey to cure'.

Keywords: Quantum metaphors, therapeutic process, gyroscopes, vital force

“Living is easy with eyes closed...” On blinded RCTs and their effect on specific and non-specific effects of complex therapeutic interventions

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Introduction: it is generally assumed that, as measured during RCTs, specific effects (SEs) and non-specific effects (NSEs) of an intervention are simultaneously observable and do not interact with each other. Here, it is argued this assumption leads to the results of RCTs (particularly for complex interventions, e.g., homeopathy) being treated far too simplistically, and is essentially incorrect.

Purpose of study: to examine if a complex intervention’s SEs and NSEs are *complementary* (in a sense derived and generalised from quantum theory), i.e., they are non-separable correlated sets of observables derived from an RCT, in which *both* are necessary to achieve a more complete understanding of an intervention’s efficacy.

Method: based on Abelian and non-Abelian algebras, a mathematical argument is developed that enables examination of the relationship between a complex intervention’s SEs and NSEs, as non-commuting observables derived from an RCT.

Results: this indicates that by treating SEs and NSEs as arising from a series of *non-commuting operations* whose order matters (as opposed to *commuting numbers* whose order does not matter), it is incorrect to assume they can be separated into simultaneously measurable, non-interacting sets of observables.

Conclusion: these results question the blinded observational stance of the RCT protocol, which justifies - and is justified by - a reductionist approach to the efficacy of complex therapeutic interventions. It also questions the legitimacy of conclusions drawn from RCTs.

In addition, generalised forms of quantum theory (without the constraints of Planck’s constant) suggest that if SE’s of an intervention and the NSEs of the consultation are complementary observable parts of an irreducibly whole therapeutic process, blinding in RCTs might then cause Heisenberg-type uncertainty between them, i.e., *one can know the SEs of an intervention and be uncertain as to the NSEs or vice versa, but one cannot know both simultaneously, with equal certainty.*

Keywords: RCTs, complex interventions, specific effects, non-specific effects, Heisenberg’s Uncertainty Principle, Abelian and non-Abelian algebras

Usage and attitudes towards homeopathy and natural remedies in general paediatrics: A cross-country overview

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Objectives: The purpose of this study was to get a deeper understanding of global trends and country differences in physicians' usage, knowledge, and attitudes regarding homeopathy and natural remedies in paediatric practice.

Method: Online survey with 582 general paediatricians and GPs treating paediatric conditions in 6 countries (Germany, Spain, Russia, Bulgaria, Colombia, Israel).

Results: Across all countries 17% of the paediatric prescriptions and drug treatment recommendations refer to phytotherapy and 15% refer to homeopathic preparations (the highest use of both treatment options in Germany, the lowest use in Israel). Natural remedies (phytotherapy and vitamins, minerals and supplements) and homeopathic preparations are most frequently used in upper respiratory tract infections, infant colic, sleep disturbances and recurrent infections. In the majority of cases they are used as complementary treatment together with conventional drugs. Both treatment options are typically used when parents are concerned about side effects of conventional drugs and when parents prefer natural remedies for themselves. Physicians express high interest in natural remedies and homeopathy, however their knowledge level is heterogeneous. Lack of proven efficacy, lack of knowledge on mechanism of action and lack of information concerning the fields where natural remedies or homeopathic preparations might be applied are the main factors that limit their usage by physicians. High usage of both treatment options is associated with a higher level of knowledge, with personal usage, with the belief in a lower risk of side effects and with lower limitations to use them due to lack of proven efficacy.

Conclusions: The study confirms high interest of physicians in using natural remedies and homeopathic preparations in children which is driven by parents' request and by the belief that these treatment options are associated with a lower risk of side effects. Due to the heterogeneous level of knowledge physicians need more information about natural remedies and homeopathy and conditions that can be treated.

Evaluation of the immediate effects of homeopathic remedies using the heart rate variability method

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Background: The autonomic nervous system (ANS) regulates visceral functions through the sympathetic and parasympathetic branches which act antagonistically to preserve a dynamic equilibrium of vital functions. In the cardiovascular system this dynamic balance results in the fluctuation between intervals of consecutive heart beats, so called heart rate variability (HRV). The higher variability is indicator of better functional state of the organism while the lower one is connected with increased morbidity and mortality.

The aim of our study was to evaluate immediate effects of homeopathic remedies over the tone of the ANS by HRV measurement in clinical cases.

Material and methods: We examined 40 patient . Their age ranged from 7 to 65 years. After homeopathic interview patients were lying fully relaxed. A basal examination was done – ECG recording for 5 minutes and analysis of HRV parameters by special software. Then patients received individually chosen remedy. Second measurement of HRV parameters was done 10 minutes after the remedy. Several parameters of HRV had been calculated: total power of HRV (TP), high frequency (HF), low frequency (LF), RRNN, pNN50, HF/LF, SDNN. The results were statistically assessed by SPSS and compared by Student's t test. Values of $P < 0.05$ were considered to indicate statistical significance. Patients filled questionnaires about level of anxiety, depressive tendencies, stress level and strategies for stress management. The same tests were done after a month.

Results: HRV was significantly increased after application of homeopathic remedy in most of the cases. Decreased HRV in some cases is most probably due to the beginning of healing crises. There is significant increase of TP, RRNN, HF after the remedy administration.

Conclusion: HRV measurement registers the immediate physiological effect of the homeopathic remedies. This will be a good contribution for the homeopathic practice as an indicator of the suitability of the remedy.

Hay Fever & Homeopathy: a case series evaluation

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Background: Seasonal allergic rhinitis (hay fever) is common and can considerably reduce the quality of life of sufferers. Despite the wide practical application and promising results in the treatment of hay fever with homeopathy, scientific proof of its effectiveness and mechanism is scarce.

Aim: To assess the clinical effectiveness of homeopathic remedies in the treatment of hay fever symptoms in everyday clinical settings.

Methods: We performed a prospective clinical audit of the eight patients in the treatment of hay fever symptoms over a period of two years (2012 and 2013) using Measure Your Medical Outcome Profile self-evaluation questionnaires (MYMOP) at baseline and again after two weeks and four weeks of homeopathic treatment.

Results: The average MyMOP scores for the eyes, nose, activity and well being had improved significantly after two and four weeks of homeopathic treatment. The average MyMOP profile improved by 2.68 after 14 days ($p < 0.0001$) and after 28 days of treatment it improved further to 2.76 ($p < 0.0001$).

Conclusions: Homeopathy treatment was able to alleviate hay fever symptoms enabling the reduction in use of conventional treatment. 25% of the patients who visited hay fever clinic felt improvement by using a single remedy while for 75% of the patients multiple remedies were used for curative results. We cannot exclude other interpretations such as placebo and regression to the mean. This study cannot be conclusive and a formal randomized clinical trial (RCT) is indicated.

Keywords: Hay fever, MyMOP

The impact of post qualification education on the professional lives of homeopaths and other complementary and alternative medicine practitioners

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There has been little research into the post qualification education of Complementary and Alternative Medicine (CAM) practitioners; however this is a contentious topic, especially in relation to the delivery of CAM practitioners' education within a university setting. A programme of Master of Science (MSc) courses in Homeopathy, Herbal Medicine and Integrated Healthcare delivered to an international group of practitioners via e-learning by the University of Central Lancashire (UCLan) offers a unique opportunity to explore how masters level education influences their professional lives. A case study exploration using focus group and interviews with lecturing staff and graduates of these courses provides insights into how post qualification education impacts on key aspects of their professional lives such as practice, professional identity and the wider community of practice (for example in the homeopathy community). This presentation will explore preliminary findings from this research project which has been undertaken in partial fulfillment of a doctorate in education qualification (EdD).

Keywords: Post qualification education, professional lives, practice, professional identity, community of practice

Cognitive enquiry on Homeopathic therapy in 2014

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In 2004 Associazione Belladonna delivered the “Enquiry on knowledge and aptitudes towards homeopathic medicine”. This multicenter cross sectional study on a sample of people seeking homeopathic care, independently carried out by a group of homeopathic physicians, has the aims to evaluate the feelings, opinions and self-reported health status in a convenience sample of Italian consumers of CAM. An ad hoc self-administered questionnaire including socio-demographic characteristics; information on feelings and opinions about CAM with a focus on homeopathy; personal experience with homeopathy, and, finally, self-reported health status (SF-12), was administered to a convenience sample of people consumers of CAM. Ten years later Fondazione Belladonna Onlus realized a new version of the questionnaire more specific and extended to patients younger than 18 years. A total of 1611 patients completed the questionnaire; 67% were adults, 33% minors and most were at a subsequent visit. Among adults most were female, young (mean age of 46 years), well educated (mean of 14 years of schooling); the reason for seeking care was for either physical or emotional conditions. Among minors the mean age was 7.8 years; about 30% were aged 0-4 years, 33% 5-9 years, 25% 10-15 years and 12% 15-18 years. The majority of minors were treated homeopathically for acute diseases (54%), chronic diseases (38%) and emotional conditions (20%). Most participants reported fair or good knowledge about homeopathy, and the right use of single remedies especially among those at subsequent visit. The subjective judgment on efficacy was good regardless of the type of health condition reported. The results observed in 2014 were consistent with those seen in 2004. The self-reported physical health status was similar to the result observed in 2004 and to the one measured elsewhere on the overall Italian population, whereas a slight lower level of health was observed concerning the mental status.

Keywords: Homeopathic care, survey, knowledge and use of treatment, health status

Hypericum perforatum to improve Pain Outcome after monosegmental Spinal stenosis surgery – Study protocol

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Background: Homeopathic *Hypericum perforatum* is known as a remedy for lancinating pain especially when nerval damage is involved. In such situations pain often radiates to different areas of the spine and might spread to different parts of the whole body. In monosegmental spinal stenosis surgery this results in the prescription of high doses of pain medications. We aimed at investigating whether *Hypericum Perforatum* C200 might lead to a decrease of conventional pain medication while maintaining pain reduction compared to conventional therapy alone.

Material and Methods: This is a monocentric double blind, randomized placebo controlled trial conducted in the Department of Neurosurgery at the Community Hospital Herdecke. Study participants are recruited from in-patients undergoing elective monosegmental Spinal stenosis surgery. From this cohort patients are randomly selected into homeopathic treatment plus usual pain management vs. placebo plus usual pain management. Three globuli of either verum or placebo will be administered after surgery every 12 hours for 5 days. The primary clinical outcome is pain reduction after three days of inpatient care measured on a visual analogue scale. Based on moderate effect sizes and allowing dropout rate of 15%, it is estimated that 50 patients will be needed for each study arms to detect a minimal clinical difference in pain reduction at 80 percent power and 5 percent significance. Statistical analysis is done by intention to treat by means of a covariance model with adjustment for baseline values and patient expectation.

Results: This trial has received ethical approval and has been reviewed by the Federal Institute for Drugs and Medical Devices (BfArM). Results are expected in 2015. Trial registration: EudraCT: 2013-001383-31.

Discussion: This study might generate immediate benefits with low risk in patients undergoing monosegmental spinal stenosis surgery in those patients treated homeopathically. Moreover results may contribute to improve post-operative pain management strategies.

Keywords: Nerval pain, *Hypericum perforatum*, RCT, study protocol

Common points, peculiarities and complementarity of two homeopathic provings' methodologies: trituration proving versus long term hahnemannian proving

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Background: Based on a multicenter pathogenetic trial carried out between January and April 2013 with four different groups in France, and using different provings' designs, this presentation describes which common points and which peculiarities were noted according to the methodologies used: trituration or long term proving.

Method: Two groups opted for the long term hahnemannian proving methodology and the two others for the C4 trituration one. All were blinded, including the coordinators of each group, only the pharmacist was aware of the remedy. The four experiments were lead at the same time. The comparison of occurrences of the noted symptoms according to the methodology has been used to build the argumentation.

Results: The plant tested, *Cuscuta Europea*, whose homeopathic properties are poorly known until now, has a very specific behavior being a total parasitic plant. This specificity together with several homeopathic symptoms, having detailed modalities, that have emerged in the four groups, offer a good basis for building an hypothesis on the inputs provided by each methodology. Some symptoms were mainly noted by the trituration provers, mostly linked to the initial energy coming from the plant, others were mainly reported by the long term provers and rather linked to the human reaction induced. The global picture was however present in both designs.

Conclusion: It seems that the use of these combined methodologies offers the opportunity to access a wider picture of the tested remedy.

Keywords: Pathogenetic trial compared methodologies, trituration, long term proving, *Cuscuta europea*

Integrative approach to the cancer patients with complementary medicine and diet in the Hospital of Lucca (Italy)

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Complementary medicine and diet in oncology – Campo di Marte Hospital, Lucca (Italy).

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Background: In order to tackle side effects of anticancer treatment an integrative oncology outpatient clinic was started in the public hospital Campo di Marte by the Homeopathic Clinic in collaboration with the Oncology Department of Lucca hospital.

Aim: Near all patients are referred by their medical oncologists. We apply pre-defined simple protocols to reduce some of the side effects of cancer therapies, indication of therapeutic sessions of acupuncture/homeopathy to decrease side effects in chemotherapy/radiotherapy and during anti-hormonal treatments such as hot flashes in order to obtain an improvement of the quality of life. All patients were also calculated BMI and when needed a diet was prescribed.

Methods: From October 2011 till April 2012 and from January to December 2014, 173 patients have been consecutively visited (36 male and 137 female); the mean age is 56.2 (35–88) years. Near all patients are referred by their medical oncologists; most were women with high level of education. Main type or localization: 105 breast cancer, 11 gynecologic cancer, 20 gastro-intestinal cancer, 2 head and neck cancer, 7 prostate cancer, 5 lung and 4 NSCLC, 4 hematologic; 25.4% of the patients had already metastasis and 60% had already used homeopathy and other CAMs. All the patients were using or have used chemo and/or radio and/or hormonal therapy. 10% of patients were using CAMs for other purposes before cancer diagnosis.

Results: Comparing the clinical conditions before and after the treatment, we have observed significant amelioration of the following symptoms of the cancer or the adverse effects of the anticancer therapies: nausea ($p=0.004$); insomnia ($p=0.003$); depression ($p=0.000$); anxiety ($p=0.000$); asthenia ($p=0.000$); hot flushes ($p=0.000$).

Conclusions: A clinic of integrative oncology seems to give the possibility to reduce the adverse effects of anticancer therapy.

Keywords: Integrative oncology; homeopathy and complementary medicine; adverse effects of chemo-radio-hormone therapy

Examination regarding the tolerability of the homochord Acidum L(+)-lacticum 4X/6X/12X/200X, dosage 3x60 drops

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Introduction: According to Reckeweg, a homochord provides broad effectiveness. Possible adverse reactions to the remedy occasionally caused by lower potencies, should be alleviated or prevented by the simultaneous intake of higher potencies. How much the efficacy and tolerability is influenced by the dosage is also under controversial discussion regarding Acidum L(+)-lacticum homochord (Sanuvis® liquid dilution).

Question: Acidum L(+)-lacticum homochord has traditionally been used at a dosage of 3x60 drops/day for over 30 years. The safety and tolerability of this homochord, in this and other dosages, was to be examined via a therapist survey. Furthermore it was analyzed which dosage is used for which illness.

Method: In April 2014, questionnaires were sent to 2000 long-time, homeopathically experienced subscribers (doctors and naturopaths), in which the application, dosage and tolerability of Acidum L(+)-lacticum drops should be documented retrospectively. The survey was concluded in July 2014. Subsequently a validated database was generated and evaluated descriptively. The indications were encoded according to ICD-10-GM (mainly: acidosis, acid-base-balance and metabolic disorders).

Results: 189 forms were processed. 30.54% of therapists had over 20 years of experience. The total number of patients was 56,000. 43.71% of the questionnaires contained information regarding the dosage of 3x60 drops. Other dosages were also evaluated. Initial aggravation is defined as a short-termed symptom increase. No initial aggravation occurred in 95.21%. 1.8% initial aggravation was observed with a 3x60 drops dosage. No side effects occurred.

Discussion: The evaluation of the 3x60 drops dosage and the other dosages indicated a good tolerability of Acidum L(+)-lacticum 4X/6X/12X/200X. This is being discussed in view of commission D's dosage recommendation of 5 drops/day for dilutions of 24X/12C and up for self-medication.

Keywords: Homochord remedy, Acidum L(+)-lacticum, drug safety, Sanuvis

Statistical analysis of cases with depression treated with classical homeopathy

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Background: Depression is a disease with high prevalence worldwide and a great number of patients enjoy homeopathic treatment for this problem.

Purpose: To collect data and make statistical analysis of depression cases from homeopathic practitioners globally.

Methods: Withoukaskas Compass (VC) online homeopathic software was used as a platform to collect homeopathic cases from homeopaths-users. From 5,406 cases with different pathologies, 156 depression cases were selected after applying certain restrictions. The prescribed remedies and reported treatment effect were analysed in relation to gender, age and geographical distribution. The treatment effect was recorded according to the homeopath's evaluation during the follow-up session, using the categories "Large improvement", "Moderate improvement", "Small improvement" and "No effect".

Results: From 5,046 cases 3,482 came from Europe (2,325 women and 1,157 men). In general 4% of female and 1.6% of male patients had depression as their main complaint. The highest percentages came from Latin America where 5.4% of the female patients had depression. Worldwide, the highest percentage in male patients (3.6%) came from North America. Russian speaking countries and India-Pakistan-Bangladesh regions appear to have the lowest percentage (1.1%). Out of 156 cases with depression, 26 patients were male and 130 female. The age distribution showed 3 peaks for female patients (~ 35, 50 and 60yrs). For male patients, peak ranges were between 45 and 50 yrs. Women reported a better response to homeopathy: 32% showed large improvement compared with only 13% in men. 30% of both men and women had moderate improvement. The first three most commonly prescribed remedies were Natrum muriaticum (22%), Ignatia amara (15%) and Pulsatilla (13%). However, better results were reported with less commonly prescribed remedies like Sepia and Staphysagria.

Conclusions: Depression is a major issue in developed countries. An internet based platform for homeopathic practitioners can offer the possibility for collection of valuable scientific evidence-based data concerning depression as well as other pathologies treated with classical homeopathy.

Keywords: Depression, homeopathic treatment, remedy effect, clinical research, medical software

Are homeopaths culturally prejudiced? Homeopathy and Medical Anthropology: Two qualitative studies from an intercultural perspective

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Introduction: According to the World Health Organization the use of traditional and complementary medicines has become a truly global phenomenon as products and practices from specific regions are now found throughout the world. Homeopathy's expansion in new locations was lately researched and discussed in medical anthropology. Aside from issues of regulation, there are important cultural implications for usage and training when such systems of medicine are deployed in different social settings. Therefore the impact upon local cultures and the implications for homeopathic practice as well as on homeopathy at large demand attention.

Description: In two separate Grounded Theory, qualitative studies, interviews were conducted with stakeholders of humanitarian aid projects of homeopathy in an intercultural context. In one study 12 educator/trainers were questioned about their experience in delivering homeopathy in a cross-cultural setting. The other study explored how 12 practising homeopaths, in five African countries, perceived their training and the challenges of application in their clinics.

Results: Interviews yielded rich data about both supporting and hindering influences in training, practice and society. Besides practical issues in training and practice, these pertained mainly to intercultural transmission. Cultural awareness, appreciation of traditional medicine and local customs are prerequisites of understanding, culturally sensitive case-taking and analysis, and perception of homeopathy by patients and public.

Conclusion: The two studies revealed several conditions for successful transmission of homeopathy into other cultures. Furthermore they highlight challenges for further investigation of homeopathy in medical anthropology. Specifically: One needs to acknowledge homeopathy as a cultural system of western origin. Frequently concepts like "Vital force" and "Miasms" employed in a non-western culture incur reinterpretations according to the cultural background. Homeopaths must review underlying principles such as basing the prescription on the patient's own words as the expression of disease; sickness is often culturally defined.

Keywords: Homeopathy, medical anthropology, treatment, training, Intercultural

Pancreatic recovery and injection free status has been achieved with insulin dependent diabetics by adding Homoeopathy to the usually prescribed mix of insulin, diet and exercise

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The majority of Type 1 Diabetics (also known as Insulin Dependent Diabetes and Juvenile Diabetes) will suffer from diabetic complications in their lifetimes.

Doctors encourage patients to maintain diabetic range HbA1c < 7.5 for children and < 7 for adults. Sadly, only 40% or less of under-40 year olds will achieve these inadequate targets, and of those that do, 50% will still suffer from complications.

The common feeling is one of hopelessness, that even if insulin is taken correctly, there is daily damage and gradual, irreversible deterioration of quality of life.

So, is there something that can be done to change this morbidity and break this cycle of despair?

Effectively used, Homoeopathy reduces the wild fluctuations in blood glucose, thereby allowing improved HbA1c control to be achieved, which minimizes or eliminates diabetic complications.

My case findings show that:

- Patients on the program with normal, or just below normal, C-Peptide levels of about 0.35+ (NR 0.4-1.5) experienced very rapid blood glucose stabilization and insulin reduction. Additionally, some patients became non-insulin requiring. Early intervention yielded the most rapid results.
- Patients who became non-insulin requiring remained stable where their HbA1c averaged around 5.8.
- Preserving and improving C-Peptide is the key to maintaining superior diabetic control.
- Stabilization of C-Peptide was achieved by maintaining normal range HbA1c levels (NR 4.0-6.0).
- For more severe cases, achieving the initial phase HbA1c target level of 5.3 to 5.5 ±0.2 resulted in C-Peptide increases, suggestive of pancreatic regeneration as well as a decrease in autoantibody activity. This in turn resulted in a reduction of insulin requirements over the medium to long term.

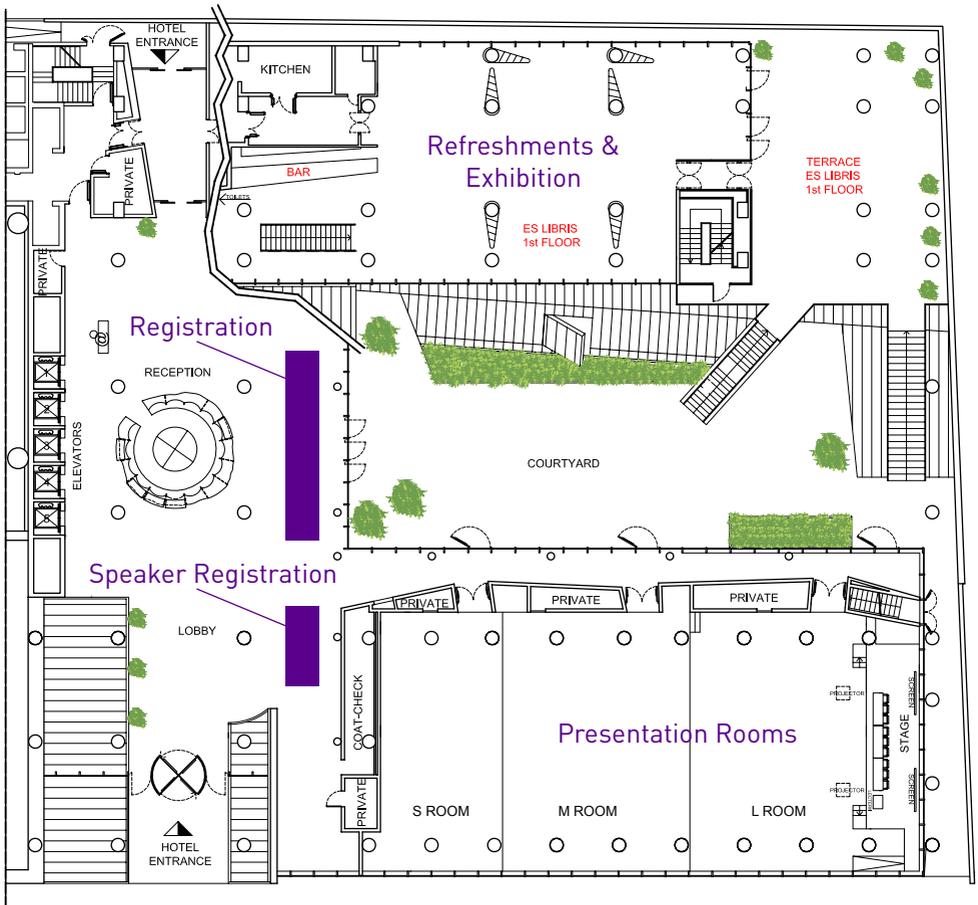
An integrated individualized program that includes Homoeopathy, diet and nutrition, exercise and insulin was used to obtain these results.

The poster will provide case studies and lab results to support the above findings.

Keywords: HbA1c, C-Peptide, insulin, DM1, Type 1 diabetes, Insulin Dependent Diabetes, juvenile diabetes, diabetes, pancreatic regeneration

Notes

Venue Plan



Thursday

- 14:00 – 17:00 Pre-Conference Workshop
- 18:00 – 20:00 Conference Registration
- 18.30 – 20.00 Welcome Drinks

Friday

- 08.00 Registration opens
- 09:00 — 09:30 Plenary Sessions – full day
Opening Ceremony
- 09:30 — 10:30 Homeopathy Research
09.30 Prof Paolo Bellavite
10.00 Dr Klaus von Ammon
- 11:00 — 12:20 Clinical Research 1
11.00 Dr Sadanandan Gopinadhan
11.20 Petter Viksveen
11.40 Dr Martien Brands
12.00 David Brule
- 14:00 — 15:20 Safety & Clinical Research
14.00 Rachel Roberts
14.20 Dr Peter Fisher
14.40 Prof Jennifer Jacobs
- 15:50 — 16:50 Poster Talks
15.50 Dr Kimberlee Blyden-Taylor
16.00 Philippa Fibert
16.10 Dr Lefteris Tapakis
16.20 Christa Raak
16.30 Alison Fixsen
16.40 Dr Helene Renoux
16.50 Dr Silvio Leite
- 17:00 — 19:00 Poster Session & Drinks
- 19:30 Rome City Centre Dinner

Saturday

- 09:10 — 10:30 Plenary Session
Lab-based Research &
Mechanism of Action
- 09.10 Dr Christian Endler
09.30 Dr Alexander Tournier
09.50 Dr Steven Cartwright
10.10 HRI, GIRI & WissHom

- Room L Plenary Session
11:00 — 12:20 Clinical Research 2
11.00 Dr Elio Rossi
11.20 Dr Francesca Talarico
11.40 Petra Klement
12.00 Dr Miek Jong

- Room L Parallel Session
14:00 — 15:20 Lab-based Research
14.00 Prof Silvana Marques de Araújo
14.40 Dr Thayna Neves Cardoso
15.00 Dr Ganesh Lakshmanan

- Room M Parallel Session
14:00 — 15:20 Proving
14.00 Prof Ashley Ross
14.20 Dr Peter Smith
14.40 Alastair Gray
15.00 Dr Jean Duckworth

- Room L Parallel Session
15:50 — 17:10 Fundamental Research
15.50 Prof Giovanni Dinelli
16.30 Dr Stephan Baumgartner
16.50 Paul Doesburg

- Room M Parallel Session
15:50 — 17:10 Proving, Methods & Clinical
15.50 Dr Jean Pierre Jansen
16.10 Dr Lex Rutten
16.30 Dr Pawan Pareek
16.50 Prof Dr Thomas Ostermann

- 20:00 Gala Dinner

Sunday

- Room L Plenary Sessions – half day
09:10 — 10:30 Lab-based Research &
Clinical Research
09.10 Dr Debora Oliosio
09.30 Dr Anna Camps
09.50 Dr Gustavo Aguilar-Velazquez
10.10 Teh Chye Phing
- 11:00 – 12:20 Clinical Research 3
11.00 Dr Rajesh Shah
11.20 Dr Rosaria Ferreri
11.40 Dr Robert Mathie
- 12:20 – 12:30 Closing ceremony



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