

HOMEOPATHY  
RESEARCH INSTITUTE

CUTTING EDGE  
RESEARCH  
IN HOMEOPATHY

BARCELONA 2013



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# 1<sup>st</sup> HRI International Homeopathy Research Conference

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## Cutting Edge Research in Homeopathy

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**Hotel Santos Porta Fira**  
Hospitalet de Llobregat  
Barcelona  
Spain

Programme  
Sponsors



31 MAY  
- 2 JUNE  
2013

# Sponsors

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# Welcome

We would like to welcome you to the Homeopathy Research Institute's 1<sup>st</sup> International Homeopathy Research Conference, ***Cutting Edge Research in Homeopathy***.

Interest in homeopathy research has grown dramatically over recent years, both within the homeopathic profession and externally. This reflects the ever-increasing emphasis being placed on evidence informed medicine across all modalities and the crucial role rigorous research is now playing in the development of homeopathy.

***Cutting Edge Research in Homeopathy*** is therefore a timely but rare event; for the first time in a decade we have 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 22 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 animal and plant-based research
- Fundamental research
- Disease prevention (homeoprophylaxis)
- Pathogenetic trials
- Health economics
- Ethics

The 'HRI Barcelona 2013' event has been organised by our Conference Organising Committee, with additional input from the Conference Advisory Committee and HRI's Scientific Advisory Committee.

HRI is delighted to be holding this landmark event in the vibrant city of Barcelona, which provides both first-class conference facilities and a great cultural experience for visitors from around the world. We would like to thank the local homeopathic community for the warm welcome we have received and 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**

Ms Kate Chatfield, Univ. of Central Lancashire (MSc Homeopathy Course Leader)  
Ms Rachel Roberts, (Chair), Homeopathy Research Institute (CEO)  
Ms Cristal Sumner, Faculty of Homeopathy & British Homeopathic Assoc. (CEO)  
Dr Alexander Tournier, Homeopathy Research Institute (Executive Director)  
Mr Petter Viksveen, Homeopathy Research Institute (Trustee)

### **Conference advisory committee**

Mr David Brule, American Medical College of Homeopathy (Faculty, Doctoral programme)  
Dr Peter Fisher, Royal London Hospital for Integrated Medicine (Clinical Director)  
Mr Stephen Gordon, European Central Council of Homeopaths (General Secretary)  
Dr Clare Relton, Univ. of Sheffield (Research Fellow) & HRI (Trustee)  
Mr Simon Wilkinson-Blake, Homeopathy Research Institute (Company Secretary & Event Organiser)

### **HRI Barcelona 2013 – Key facts**

- Over 150 abstracts submitted
- 38 oral presentations and 25 poster presentations delivered in a programme comprising 8 plenary sessions, 2 parallel sessions and 1 poster session
- Over 170 delegates attending, representing more than 30 countries

### **About HRI**

The Homeopathy Research Institute (HRI) is an innovative charity, created to address the need for reliable 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 five active research projects. These range from a pragmatic randomised controlled trial assessing homeopathy for the treatment of children diagnosed with ADHD, to investigating the effects of succussion on the physico-chemical properties of ultra-high dilutions.

*“Homeopathy will remain controversial until high quality research studies provide definitive answers about how well homeopathy works for specific clinical conditions, or the mechanism of action of highly diluted substances is finally understood. HRI is working with experts worldwide to promote research in both these directions.”*

**Dr Alexander Tournier PhD – HRI Executive Director**

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 and Complementary and Alternative Medicine research, provide the strong scientific foundations essential to our work.

## Members of the HRI Scientific Advisory Committee



**Dr Stephan Baumgartner** PhD

Lecturer, Institute of Complementary Medicine KIKOM, University of Bern and Senior Researcher, Society for Cancer Research, Arlesheim, Switzerland



**Dr Iris Bell** MD PhD

Professor, Dept. of Family and Community Medicine, The University of Arizona College of Medicine, Tucson, Arizona, USA



**Dr Peter Fisher** MA MB BChir FRCP FFHom

Clinical Director and Director of Research, Royal London Hospital for Integrated Medicine, University College London Hospitals, NHS Trust, UK



**Dr Hugh MacPherson** BSc PhD

Senior Research Fellow, Department of Health Sciences, University of York, UK



**Dr Robert Mathie** BSc PhD

Research Development Adviser, British Homeopathic Association, Luton, UK



**Dr Clare Relton** MSc PhD RSHom FSHom

Research Fellow, School for Health and Related Research, University of Sheffield, UK



**Dr Elizabeth Thompson** BAOxon MBBS MRCP FFHom

Lead clinician and Academic director, Bristol Homeopathic Hospital, UK



**Dr Alexander Tournier** BScCantab PhD LCHE RSHom

HRI Executive Director and Independent researcher, UK

*"We believe high quality scientific research in homeopathy to be both necessary and achievable."*

**Ms Rachel Roberts – HRI Chief Executive**

For more information visit [www.homeoinst.org](http://www.homeoinst.org)

# Programme

Conference Registration

THURSDAY 30 MAY 2013

18:00 – 20:00 Registration

Day 1 – Cutting Edge Research in Homeopathy

FRIDAY 31 MAY 2013

Las Arenas IV Plenary Session

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09:00 — 09:30 Opening Ceremony

09:30 — 10:30 Homeopathy Research – the State of Play and the Way Forward

Chair: Dr Elizabeth Thompson

09:30 Dr Peter Fisher, UK. *Cutting edge to clinical effectiveness: the implications of recent theoretical and research findings in homeopathy*

10:00 Dr Stephan Baumgartner, Switzerland. *Homeopathic basic research: State of the research and quests for the future*

10:30 — 11:00 Coffee

Las Arenas IV Parallel Session

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11:00 — 12:20 Pathogenetic trials & Clinical research

Chair: Helene Renoux

11:00 Jeremy Sherr, Tanzania. *Do pathogenetic trials produce consistent and recognisable symptom pictures? Results from a pilot pathogenetic trial study*

11:20 Alastair Gray, Australia. *Harnessing the unmined data rich resources of homeopathic provings: an overview of replicated provings, creating a common language and a method forward*

11:40 Dr José Enrique Eizayaga, Argentina. *Sensitivity, specificity and likelihood ratio of symptoms in patients with good therapeutic response to Lycopodium, compared to patients with good response to treatment with other homeopathic medicines*

12:00 Dr Lex Rutten, The Netherlands. *Will this medicine work for me? Towards a scientific answer*

Las Arenas I Parallel Session

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11:00 — 12:20 Experimental Research

Chair: Prof Leoni Bonamin

- 11:00** **Dr Giovanni Dinelli**, Italy. *Effects of homeopathic treatments on the cellular metabolism of wheat: validation of microarrays data by quantitative real-time PCR (qPCR)*
- 11:20** **Dr Tim Jäger**, Switzerland. *Comparative study of two bioassays with weakened duckweed and yeast treated with homeopathic preparations*
- 11: 40** **Dr Maria Olga Kokornaczyk**, Italy. *Might evaporation-induced droplet patterns serve in agro-homeopathic research and support experimental trials?*
- 12:00** **Dr Miek Jong**, The Netherlands. *Effectiveness of complex homeopathic medicinal products in the treatment of children with painful teething*

12:30 — 14:00 Buffet Lunch

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**Las Arenas IV** **Plenary Session**

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**14:00 — 15:20** **Health economics & Clinical research**

**Chair: Dr Thomas Peinbauer**

- 14:00** **Dr Elizabeth Thompson**, UK. *Economic evaluation of the Bristol Homeopathic Hospital: Final results of the BISCUIT feasibility study*
- 14:30** **Petter Viksveen**, Norway. *Economic evaluations of homeopathy: A review*
- 15:00** **Dr Laurence Terzan**, France. *The impact in term of public health of the sleep, anxiety and depressive disorders management by physicians prescribing homeopathic medicine in France. The EPI3 programme*

15:20 — 15:50 Coffee

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**Las Arenas IV** **Plenary Session**

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**15:50 — 16:50** **Poster Talks**

**Chair: Stephen Gordon**

- 15:50** **Dr Theodoros Lilas**, Greece. *Assessment of a new decision support expert system in headaches cases*
- 16:00** **Dr Lionel Milgrom**, UK. *“It’s the consultation, stupid!”...Isn’t it?’ Complementarity and the shortcomings of RCTs*
- 16:10** **Dr Susanne Pannek-Rademacher**, Switzerland. *Acceptance of homeopathy by the staff of an intensive care unit: a service evaluation*
- 16:20** **Dr Laurence Terzan**, France. *Clinical Evaluation of the Effects of Arnicare Gel, a Homeopathic Preparation in Sport related pain and stiffness*

- 16:30** **Dr Joyce Frye**, USA. *Potassium dichromate (homeopathic Kali bichromicum) in the community hospital. Intensive Care Unit setting: a review of sixteen cases*
- 16:40** **Miranda Castro**, USA. *A research tool for homeopathic practice*

**Las Arenas I**

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- 17:00 — 19:00** **Poster Session**
- 19:30** **Evening Excursion into Barcelona City Centre**

**Day 2 – Cutting Edge Research in Homeopathy**

**SATURDAY 1 JUNE 2013**

**Las Arenas IV** **Plenary Session**

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- 09:00 — 10:20** **Research theory & Clinical research**  
**Chair: Dr Peter Fisher**
- 09.00** **Dr Robert Mathie**, UK. *Model validity of randomised placebo-controlled trials of individualised homeopathic treatment*
- 09.20** **Dr Sofia Wenna**, Brazil. *Homeopathic Medication in Pulmonary Tuberculosis Treatment, Clinical Evolution, and Drug-Resistance: a Randomized, Double Blind Clinical Trial*
- 09.40** **Prof Jürgen Pannek**, Switzerland. *Use of homeopathy for prophylaxis of urinary tract infections in patients with neurogenic bladder dysfunction*
- 10.00** **Dr Christien Klein-Laansma**, The Netherlands. *Towards an evidence-based homeopathic treatment for PMS*
- 10:20 – 10:50** Coffee

**Las Arenas IV** **Plenary Session**

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- 10:50 — 12:30** **Laboratory Studies, Veterinary & Ethics**  
**Chair: Prof Dr Christian Endler**
- 10.50** **Prof Thomas Ostermann**, Germany. *In-vitro experiments to investigate the effects of homeopathic drugs for chronic aggressive periodontitis by lymphocyte migration activity*
- 11.10** **Dr Debora Olioso**, Italy. *Study of Gelsemium sempervirens in a neurocyte model. An update*
- 11.30** **Dr Ghada Alsaleh**, France. *In vitro testing of highly diluted cytokines and specific nucleotide acid sequences applied in micro-immunotherapy for rheumatoid arthritis*
- 11.50** **David Eyles**, UK. *Amelioration of pain and distress in tail-ringed lambs using homeopathy*
- 12.10** **Dr Delny Britton**, UK. *Homeopathic research involving animals: the case for cutting edge ethics*

12.30 – 14.00 Lunch

**Las Arenas IV Parallel Session**

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**14:00 — 15:20**

**Experimental Research**

**Chair: Dr Robert Mathie**

**14:00**

**Prof Christian Endler**, Austria. *Highland amphibians and extremely diluted thyroxine*

**14:40**

**Prof Leoni Villano Bonamin**, Brazil. *Modulation of chronic inflammation response to *Leishmania (L.) amazonensis* by Thymulin 5CH in mice*

**15:20**

**Dr Yakov Freed**, Israel. *Bridging the gap between the homeopathic world and the conservative medical world – Test case in rats*

**Las Arenas I**

**Parallel Session**

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**14:00 — 15:20**

**Qualitative & Clinical Research**

**Chair: Dr Elio Rossi**

**14:00**

**Dr Gualberto Diaz-Saez**, Spain. *Use and knowledge of homeopathic drugs by the general population in Spain*

**14:20**

**Dr Ramona Jurcau**, Romania. *The influence of *Aconitum Napellus* versus placebo on anxiety and salivary cortisol, in stress induced by intense and short term physical effort*

**14:40**

**Dr Shaik Shamsur Rahman**, UAE. *Clinical trial of lipoma*

**15:00**

**Petra Klement**, Germany. *Treatment of nervous complaints and exhaustion with the homeopathic medicinal product *Manuia* – Results of a cohort study*

15:20 — 15:50

Coffee

**Las Arenas IV**

**Plenary Session**

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**15:50 — 17:10**

**Fundamental Research**

**Chair: Dr Stephan Baumgartner**

**15:50**

**Prof Iris Bell**, USA. *Integrative nanomedicine: Homeopathic remedies as source and silica nanoparticles acting as danger signals for nonlinear complex adaptive systems*

**16:30**

**Dr Alexander Tournier**, UK. *Quantum coherence domains and nanoparticles – one and the same thing?*

**16:50**

**Dr Steven Cartwright**, UK. *Pyridinium-N-phenolates as molecular probes of serially diluted and agitated solutions: preliminary results*

**20:00**

**Gala Dinner**

<b>Las Arenas IV</b>	<b>Plenary Session</b>
<b>09:10 — 10:30</b>	<b>Clinical Research</b>
	<b>Chair: Dr Gustavo Bracho</b>
<b>09:10</b>	<b>Dr Elio Rossi</b> , Italy. <i>Homeopathy in the public health system: the experience in Lucca Hospital (1998-2011)</i>
<b>09:50</b>	<b>David Brule</b> , Canada. <i>Feasibility and design of an open label pilot study of homeopathic treatment of attention deficit hyperactivity disorder</i>
<b>10:10</b>	<b>Philippa Fibert</b> , UK. <i>Is homeopathic treatment as an effective intervention for children with a diagnosis of attention deficit hyperactivity disorder (ADHD)?</i>
10:30-11:00	Coffee
<b>Las Arenas IV</b>	<b>Plenary Session</b>
<b>11:00 – 12.20</b>	<b>Homeoprophylaxis</b>
	<b>Chair: Dr Concepción Campa</b>
<b>11:00</b>	<b>Prof Gustavo Bracho</b> , Cuba. <i>Homeoprophylaxis Evidence from basic research and practical applications</i>
<b>11:40</b>	<b>Dr Sandra Salles</b> , Brazil. <i>Protocol for prevention and treatment of dengue fever and its complications</i>
<b>12:00</b>	<b>Dr Gadugu Srinivasulu</b> , India. <i>An open observational study on efficacy of miasmatic prescription in the prevention of Japanese encephalitis</i>
<b>12:20 – 12:30</b>	<b>Closing ceremony</b>
<b>12:30 – 14:00</b>	<b>Optional Buffet lunch</b>

# Keynote Speaker Biographies



**Dr Stephan Baumgartner**, *Lecturer, Institute of Complementary Medicine KIKOM, University of Bern and Senior Researcher, Society for Cancer Research, Arlesheim, Switzerland.*

Dr Baumgartner's research focuses on the potentiation procedure, using bioassays and physicochemical investigations. He is a founding member of The International Society of Complementary Medicine Research and a vice-president of the International Group for Research on Infinitesimal Doses (GIRI).



**Dr Iris Bell**, *Professor, Dept. of Family and Community Medicine, University of Arizona College of Medicine, Tucson, AZ, USA*

A researcher in holistic medicine for over 30 years, Dr Bell is Professor of Family and Community Medicine at the University of Arizona College of Medicine. She will be contributing to the Conference remotely from her base in the US.



**Dr Gustavo Bracho**, *Head of Homeopathy and Biotherapeutic Projects, Finlay Institute, Havana, Cuba*

Dr Bracho is well-known for his work on homeoprophylaxis for infectious diseases ranging from Leptospirosis to Influenza. His background as an expert in adjuvants for vaccine development at the Finlay Institute in Cuba gives him a unique perspective on infectious disease prevention.



**Prof Dr Christian Endler**, *Head and Scientific Director, Interuniversity College for Health and Development Graz, Castle of Seggau, Austria*

Prof Endler's research interests have included development of the amphibian model for in vitro investigation of the action of ultra high dilutions. He is a member of the Board of the International Group for Research on Infinitesimal Doses (GIRI).



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

Accredited as a specialist in both homeopathy and rheumatology, Dr Fisher is a member of WHO's Expert Advisory Panel on Traditional and Complementary Medicine and Editor-in-Chief of the international journal, *Homeopathy*, published by Elsevier.



**Prof Sandra Mazzoli**, *Professor, University for Applied Microbiology and Clinical Microbiology, Florence, Italy*

A microbiologist (virologist and bacteriologist) also working in the field of mucosal immunity, Prof Mazzoli has been chief of the STDs centre of the local health service in Florence for 30 years. She is an expert on HPV especially in males and has been conducting research into the effectiveness of micro-immunotherapy for STDs.



**Dr Elio Rossi**, *Director of Homeopathic Clinic, Provincial Hospital of Lucca, Italy, Regional Centre of Reference, Tuscany Network for Integrative Medicine*

Dr Rossi has more than 30 years' experience in homeopathic, 15 of them in the Public National Health System. His clinical research publications have addressed topics such as homeopathic aggravation and adverse effects, cost-benefit, and long term outcome of atopic diseases.



**Dr Elizabeth Thompson**, *Lead Clinician and Academic Director, Bristol Homeopathic Hospital, UK*

Dr Thompson is a Consultant Homeopathic Physician specialising in oncology. Her clinical research interests have focused on the possible role for homeopathy as a novel approach to symptom control in the cancer patient and in particular managing side effects of cancer treatments.

# Pre-Conference Workshops Programme

Research Skills for Beginners

THURSDAY 30 MAY 2013

- 14:00 – 14:40**                      **Demystifying research publications – Kate Chatfield**
- Using a real example, Kate will show participants how to make sense of a research paper. Together you will look at issues such as how to assess the quality of the research, how to spot bias, what the statistics actually tell us, and the implications of the study.
- 14.40 – 15.20**                      **How to write a protocol – Dr Clare Relton**
- Learn how to write a protocol (a plan to conduct research) which: a) gets funded, b) is workable, and c) helps produce meaningful answers/ results. Clare will share what she has learnt about this topic over the last 8 years of writing protocols.
- 15:20 – 15:40                      Coffee
- 15:40 – 16:20**                      **Choosing your trial design – perfect fit or round pegs in square holes? – Dr Elizabeth Thompson**
- Liz will draw on her experience of running different trial designs and looking at the kind of evidence that can help to develop clinical services. She is very happy to take questions in what should be an interactive session, so don't be shy.
- 16.20 – 17.00**                      **Experimental Basic Research in Homeopathy: an Introduction – Dr Stephan Baumgartner**
- During this comprehensive workshop Stephan will introduce you to key sources of basic research literature (databases, publication providers and journals which publish homeopathic basic research), plus the most active research working groups worldwide, relevant meetings, conferences and researchers' organisations. Stephan will also discuss key issues such as publication standards for homeopathic basic research, standards for solid experimental work and the specific challenges in basic research in homeopathy.

# Presenter Biographies



**Dr Stephan Baumgartner**, *Lecturer, Institute of Complementary Medicine KIKOM, University of Bern and Senior Researcher, Society for Cancer Research, Arlesheim, Switzerland*

Dr Baumgartner's research focuses on the potentiation procedure, using bioassays and physiochemical investigations. He is a founding member of The International Society of Complementary Medicine Research and a vice-president of the International Group for Research on Infinitesimal Doses (GIRI).



**Kate Chatfield**, *Course Leader MSc Integrated Healthcare, School of Health, University of Central Lancashire, UK*

Ms Chatfield is course leader for MSc Integrated Healthcare (e-learning) at the University of Central Lancashire, UK. She has been involved in homeopathy research for many years and, in her role as tutor, has designed and delivered courses in research methods at many different levels. Currently Kate is responsible for teaching introductory and advanced research methods to postgraduate students on a number of MSc courses at UCLan, including MSc Homeopathy. Kate has a background in philosophy and her current research involves analysis of ethical challenges in complementary and alternative medicine.



**Dr Clare Relton**, *Research Fellow, School for Health and Related Research, University of Sheffield, UK*

Dr Relton originally studied Philosophy at the University of Newcastle upon Tyne (UK). She worked as a homeopath in the NHS 1998-2005 and was made Fellow of the Society of Homeopaths in 2009. She was awarded a Department of Health Pre Doctoral Training Fellowship from 2003 to 2008, obtained her MSc (Health Services Research) in 2004 and received her PhD (Clinical Trial Design) in 2009. Dr Relton is involved in research in obesity, chronic pain, IBS, and pragmatic clinical trial design.



**Dr Elizabeth Thompson**, *Lead Clinician/Consultant Homeopathic Physician and Honorary Senior Lecturer in Palliative Medicine, Bristol Homeopathic Hospital, UK*

Dr Thompson is a Consultant Homeopathic Physician specialising in oncology. Her clinical research interests have focused on the possible role for homeopathy as a novel approach to symptom control in the cancer patient and in particular managing side effects of cancer treatments.

# Exhibitors



Deutsche Homöopathie-Union (DHU) is an affiliated company of Schwabe Pharmaceuticals Group, owned by the Schwabe family since its creation and managed today by the 5th generation.

The DHU global business encompasses affiliated companies and partners in more than 40 countries.

In 2011, DHU launched a global umbrella brand for children's soft and mild disorders and dysfunctions under one common identity – '*Mama Natura*<sup>®</sup>'; the only international range of naturally effective treatments developed especially for babies & children.

The *Mama Natura*<sup>®</sup> range was developed based on the essence of Mother Nature, with the welfare and health of babies and children in mind. The idea of natural remedies specifically for children is highly relevant as the *Mama Natura*<sup>®</sup> products offer the key benefits of naturalness and gentleness with no side effects.



VithoukasCompass.com is a new, scientifically developed expert system designed to effectively assist practitioners of all levels in deciding which remedy to prescribe to their patients. Its "brain" is based on the exhaustive study of thousands of real cases and the unique method of classical homeopathy master George Vithoukas. It incorporates numerous innovative functions and valuable content to enhance your productivity, sharpen your skills and help you collaborate with your colleagues. It is a multilanguage live system constantly being improved based upon users' analysis and results aiming to achieve ongoing research into the complex nature of homeopathy.

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# Oral Presentations

Dr Ghada Alsaleh

Sat 1 June, 11.30

## ***In vitro* testing of highly diluted cytokines and specific nucleotide acid sequences applied in micro-immunotherapy for rheumatoid arthritis**

Ghada Alsaleh<sup>1</sup>, Etienne Capieaux<sup>2</sup>, Dominique Wachsmann<sup>1</sup>, Pierre Dorfman<sup>2</sup>

<sup>1</sup> Laboratoire Physiopathologie des Arthrites, EA4438, Université de Strasbourg, UFR Sciences Pharmaceutiques, Illkirch, France

<sup>2</sup> Labo'Life Belgium, Gembloux, Belgium

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Background: TNF- $\alpha$  and IL-6 are key inflammatory factors in rheumatoid arthritis (RA) and constitute targets for the development of anti-inflammatory drugs. Rather than apply antagonist strategies, the micro-immunotherapy approach is based on the use of very low doses and highly diluted cytokines and specific nucleotide acid sequences (SNA<sup>®</sup>) which, administered sequentially, are intended to reduce synovial inflammation and to regulate auto-immune disorders associated with RA.

Objectives: the aim of these *in vitro* studies was double: i) assess on various cellular models the biological activities of serial homeopathic dilutions of cytokines and SNA developed for a new Micro-Immunotherapy medication (2L<sup>®</sup>PR) and ii) investigate their mechanism of action by using biomolecular tools.

Methods: a first set of experiments was performed on human fibroblast-like synoviocytes (FLS) isolated from RA patients and cultured in standardized conditions. Different protocols of treatment were applied to examine the potential anti-inflammatory effect of major cytokines (IL-1, IL-2, IL-6, IL-10, IFN- $\gamma$ , TNF- $\alpha$ ) administered in a large range of dilutions (3CH to 27CH). Homeopathic solutions were tested alone or in association on FLS activated with various concentrations of TNF- $\alpha$  (0.1, 1 and 5 ng/ml).

Preliminary tests were carried out on non-activated FLS. IL-6 release was determined in cell supernatants by ELISA. In addition, the anti-inflammatory effect of TNF-alpha 5CH formulated in homeopathic pellets was controlled on this FLS model. In a second set of experiments, high dilutions (HD) of SNA sequences designed to target the gene of two major proteins involved in RA (TNF- $\alpha$  and its receptor p55) were investigated on a LPS-stimulated macrophage (THP1) model. TNF- $\alpha$  synthesis and release were determined by RT-PCR (mRNA) and ELISA (protein), after stimulation by LPS (1 $\mu$ g/ml). Results: in the first set of experiments, we observed that priming of cells with TNF- $\alpha$  and IL-6 dilutions down-regulated IL-6 release by TNF- $\alpha$  activated FLS. The same result was obtained with pellets of TNF- $\alpha$  5CH. This effect was not obtained with other major cytokines such as IL-1, IL-Ra, IL-2, IL-10, and IFN- $\gamma$ . In the second set of experiments, we demonstrated that HD of both SNA significantly down-regulated TNF- $\alpha$  synthesis and release. This biological activity was showed to be specific (no effect of HD scramble SNA) and related to the level of dilution (maximal effect with higher

dilutions). Unexpectedly, a reproducible stimulation effect of HD water was obtained in the LPS-stimulated THP1 model. This biological activity of agitated water (negative control) was not detected in TNF- $\alpha$  activated FLS model.

Conclusions: these findings indicate that homeopathic dilutions of TNF- $\alpha$  and IL-6 can regulate IL-6 release by synoviocytes and that highly diluted SNA RA can regulate TNF- $\alpha$  synthesis and release by LPS-stimulated THP1. This exploratory work supports the hypothesis that micro-immunotherapy may represent an alternative therapeutic approach for RA and that high dilutions act in modulating mRNA expression of the targeted genes.

Keywords: Specific Nucleic Acids (SNA®); Cytokines; Micro-Immunotherapy; Cellular models; Rheumatoid arthritis

Conflict of interest: Ghada Alsaleh and Dominique Wachsmann declare there is no conflict of interest. Etienne Capieaux was formerly Scientific Director at Labo'Life Belgium and Pierre Dorfman is currently Medical Director at Labo'Life.

Financial support: This project was supported by the Walloon Region (General Direction for Technologies, Research and Energy), Grant n°5899 and Labo'Life Belgium. Authors declare they had full access to all the data in this study and they take complete responsibility for the integrity of the data and the accuracy of the data analysis.

**Homeopathic Basic Research: State of the Research and Quests for the Future**

Stephan Baumgartner, PhD

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Homeopathy relies on two basic tenets: the simile principle and the potentisation procedure. The validity of these presumptions is being questioned, since there seems to be no obvious scientific basis on which to justify their application in pharmacy and medicine. Nevertheless, homeopathy is being widely practised and many patients, as well as practitioners, are satisfied with the clinical outcomes achieved in daily practice. However, the lack of understanding leads not only to problems with legal recognition, integration into public healthcare and reimbursement by health insurances, but also hampers further development and optimisation of homeopathic therapy. Therefore, development of a deeper understanding of the two basic tenets of homeopathy is of ultimate importance.

Only a few basic research projects seem to have been performed to investigate the simile principle. The fundamental pioneering work of van Wijk and Wiegant so far has not been taken up by any other research team. Determination of the areas of applicability of the simile principle is an important task, as is the elucidation of the mode of action.

Comparably more research has been carried out to investigate the potentisation procedure. However, I currently do not know of any laboratory model that reproducibly yields specific effects of highly diluted homeopathic potencies in different laboratories, and I do not know any theory that would satisfyingly explain any such specific effects of ultramolecular potencies. Thus the following two main topics have to be addressed in the coming years: development of optimal laboratory models to identify specificity and reproducibility of homeopathic effects, and identification of the long-sought-for mode of action of highly diluted potencies.

Are there any experimental laboratory systems that reliably yield reproducible evidence for specific effects of homeopathic potencies? To resolve this question, it will be necessary to investigate various model systems in parallel in different laboratories to determine any necessary and sufficient conditions for successful reproducibility; until now, according to my knowledge, corresponding parameters could be identified for three model systems only. Optimisation of the laboratory models involves the choice of the test organism in a defined physiological state, an adapted potentised substance in an adequate potency level applied in an optimal route and dosage, as well as optimal outcome measures. Furthermore, it will be necessary to develop model systems that not only demonstrate empirical effects of single homeopathic remedies, but also differentiate effects of different potentised substances. Thus, model systems have to be simple and cost-effective to enable easy implementation in other laboratories, and to allow multiple parameters to be tested in parallel (e.g. different substances and/or potency levels). Finally, stability of any experimental system used must be demonstrated by systematic negative control (SNC) experiments on a routine basis.

Identification of the mode of action of highly diluted homeopathic remedies is the ultimate goal of homeopathic basic research. This involves determination of the general type of interaction present between homeopathic potency and test organism: local material-like, force-like, or non-local entanglement-like. This not only implies precise investigations of homeopathic preparations by sophisticated physicochemical methods, but also experimental approaches to test Hahnemann's premise of force-like effects of homeopathic potencies. Furthermore, the general nature of the effects of homeopathic potencies has to be determined: reproducibly deterministic, chaotic or inherently indeterministic. Solid experimental data regarding these questions will enable development of a precise theoretical framework, ultimately resulting in a thorough understanding of homeopathic effects.

**Integrative Nanomedicine: Homeopathic Remedies as Source and Silica Nanoparticles Acting as Danger Signals for Nonlinear Complex Adaptive Systems**

Iris R. Bell, MD PhD, The University of Arizona

The alleged “implausibility” of homeopathic medicines is a foundation for attacks on homeopathy. Skeptics insist that homeopathic medicines are too dilute to contain any residual material from their mineral, plant, or animal sources or exert effects. Nonetheless, multiple studies on cells, animals, plants, and human subjects have demonstrated biological effects of remedies.

Research laboratories have shown that 6 different metal remedies and 3 different plant remedies contain persistent remedy source nanoparticles (NPs) from low to high potencies beyond Avogadro’s number for bulk form materials. Multiple laboratories also have documented the ability of succussion in glass containers to release measurable amounts of silicon and silica into solution. Chikramane et al (2012) showed that succussion can generate heterogeneous accumulation and layers of remedy source nanoparticles that lead to physical transfer carryover of nanoparticles from container to container during the “serial dilution” procedures, even though bulk form source materials may be diluted away. In addition, Das et al (2013) demonstrated that homeopathic plant mother tinctures can biosynthesize silver nanoparticles from precursors, just as plant extracts can biosynthesize silica nanoparticles from silica precursors.

Nanoparticles could explain many puzzling observations and variability from study to study in homeopathic research. Elia et al have found aging-related effects in homeopathically-prepared remedies in terms of heat release and electrical conductivity changes after storage – observations that overlap nanoparticle phenomena of aging and Ostwald ripening. Some homeopathically-prepared materials, e.g., specific bacteria nanoparticulates, also emit detectable electromagnetic signals after certain dilution-succussion processes. Certain spectroscopy studies showed unique patterns for homeopathically-prepared remedies compared with control solvents (succussed and nonsuccussed). Some investigators have also interpreted findings from proving studies as indications of quantum mechanical properties of remedies. NPs have enhanced bioavailability, adsorptive capabilities, adjuvant reactivity, electromagnetic, optical, thermal, biochemical, and quantum properties compared with their bulk forms. Different concentrations of ethanol, variations in pH, temperature, and glassware, as well as dilution sampling and succussions (or sonication, vortexing) will lead to different sizes, shapes, surface charges, and properties of the resultant nanostructures. Even minor variations in the latter variables could contribute variability to remedy actions. This talk discusses implications of the homeopathic nanoparticulate findings for a biological signaling model of the homeopathic remedy nanostructures in initiating a cascade of endogenously amplified adaptations and cross-adaptations across the organism as a whole.

Homeopathic remedy manufacturing probably generates NPs by a crude “top-down” mechanical grinding in lactose and/or succussions in room temperature ethanolic solutions within borosilicate glass containers. Silica nanostructures could serve as remedy source NP drug delivery vehicles and nonspecific biological amplifiers. Nanoparticles induce self-organized adaptive changes in the organism at nontoxic doses (hormesis), serving as salient, low level danger signals to the biological stress response networks. Release of exosomes and activation of stress response effectors, including heat shock proteins, inflammasomes, cytokines and neuroendocrine networks, would initiate and progressively amplify beneficial compensatory reactions. Thus, homeopathy may represent the earliest practical development of “integrative nanomedicine” for using pulsed doses of nanoparticles from natural source materials safely and effectively in treating a wide range of acute and chronic clinical conditions.

**Modulation of chronic inflammation response to *Leishmania (L.) amazonensis* by Thymulin 5CH in mice**

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In previous studies, we observed that thymulin 5CH could modulate the chronic inflammation response to BCG in an experimental infection, by increasing peritoneal B1 stem cells differentiation into phagocytes and improving bacilli phagocytosis efficiency into the infection site. Herein, the same protocol was used to study the effects of thymulin 5CH in a protozoan experimental infection. Male Balb/c mice were orally treated with thymulin 5CH or vehicle during 60 days after the subcutaneous inoculation of  $2 \times 10^5$  units of *Leishmania (L.) amazonensis* into the footpad. Then, washing inflammatory cell suspension from peritoneal cavity and spleen were harvested to be identified and quantified by flow cytometry and the tissue of infection site, as well as the local lymph node were harvested for histological examination and quantification. Treated mice presented increase in B1 stem cells percentage in peritoneal washing fluid and in spleen ( $p=0.0001$ ), in relation to other cell types, and more organized and exuberant inflammation response in the infection site, with decrease in the number of parasites per field ( $p=0.05$ ). No difference was seen in local lymph node histology. The results show that thymulin 5CH is able to improve B1 stem cell activation and *Leishmania (L.) amazonensis* phagocytosis efficiency in mice, similarly to that observed previously in BCG experimental infection.

**Homeoprophylaxis: Evidences from basic research and practical applications.**

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Homeo-Prophylaxis (HP), has been one of the more questioned application of homeopathy despite it also could be considered one of the most revolutionary uses in terms of benefits for health quality. Although the protection effects and impact (effectiveness and efficacy) are frequently difficult to demonstrate, the lack of scientific research, among other factors, hinder the acceptance and implementation of HP but also limits the possibility of running proper clinical studies. In order to breakdown this close circle, in vitro experiment, animal's models and clinical evaluation should be combined with the current knowledge and evaluation methodologies of the immune system.

A summary of unpublished results from basic research experiments on the effects of homeopathically diluted biological material as prophylactic formulations on in vitro and animal models will be presented. According to the results, an approach to underlying immune mechanisms could be proposed and discussed.

Results from 5 years follow up of large scale Leptospirosis HP intervention will be complemented and analysed. Further clinical evaluation of HP on other epidemic diseases at large scale could be presented.

An integral analysis of evidence coming from experimental model and clinical testing suggest that HP could be consider in fact as a very promising and potent tool to face infectious diseases in the context of current global situation.

**Homeopathic research involving animals: the case for cutting edge ethics**

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Research into homeopathy is undergoing a welcome and rapid period of growth driven by the increasing need to provide evidence for the therapy's effectiveness and mode of action.

In mainstream medicine animal-based research has become integral to the development of new drugs and treatments, despite only modest success in extrapolating findings in animals to humans. Homeopathy, based on provings and clinical confirmation of the Law of Similars, is not subject to such shortcomings. Nevertheless animals with artificially induced ailments have been used by researchers with the aim of supplementing existing homeopathic knowledge and to demonstrate that homeopathy 'works' under laboratory conditions.

A search of several homeopathic and medical databases shows that such animal-based research encompasses a wide range of physical and psychological conditions and has involved procedures likely to cause moderate to severe suffering in the experimental animal. Whilst the rights, dignity and welfare of humans participating in homeopathic research are safeguarded in line with standards laid down in the Declaration of Helsinki, international standards of protection for experimental animals vary widely and are markedly less stringent. Homeopathy has its basis in sound ethics, nevertheless increased interest in and funding for research in this field could lead to increased animal-based research at a time when, in the UK at least, public trust in the rules governing the controversial practice is falling and calls for alternatives on the rise.

This paper examines some of the scientific, ethical and political imperatives regarding animals in homeopathic research, including advances in our understanding of the capacity for suffering in laboratory animals, societal drivers to replace, reduce and refine animal experiments and the opportunity to demonstrate cutting edge ethics in the advancement of homeopathic knowledge.

## **Feasibility and design of an open label pilot study of homeopathic treatment of attention deficit hyperactivity disorder**

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### Purpose

An open-label pilot study of individualized homeopathy for attention deficit hyperactivity disorder (ADHD) was conducted in order to assess potential for a future, more scientifically rigorous study. Three key objectives were:

1. To develop estimates of treatment effects;
2. To determine the time, number of consultations and the number of different homeopathic remedies needed for a statistically significant improvement in ADHD symptoms;
3. To assess recruitment plan and outcome measure feasibility.

### Methods

Participants were recruited through the clinical study staff, community advertisement and outreach, and underwent a diagnostic assessment by the study psychologist. Participants with ADHD aged 6-16 years completed 10 individualized homeopathic consultations. Effects on ADHD symptoms were assessed using the Conners 3—Parent questionnaire and self-report symptoms using the MYMOP2. Data were analyzed with SPSS statistical software. The pre- and post-study difference in Conners Global Index (CGI-P) T-score was evaluated for each participant using the Conners Reliable Change Index. Group T-score medians were compared with the Wilcoxon Signed Rank test.

### Results

36 Participants were enrolled over 11 months. Data collection has concluded for 28 participants and will be completed for all participants by the end of 2012. 23/28 (82%) completed all 10 consultations in a median of 11.75 months (range 10.0-16.5). 19/28 (68%) had a statistically significant improvement in the primary outcome (CGI-P T-score), first occurring after a mean of 4.0 visits (range 2-10) and after trying on average 1.68 remedies (range 1-5). Overall CGI-P T-scores for participants completing at least two data points decreased from a baseline median of 85.5 to 73.5 at the end of the participant enrolment in the study ( $p < 0.001$ ). No serious adverse events possibly or likely related to the therapy were reported. 89% of the Conners 3 - Parent questionnaires were completed. MYMOP2 was deemed not feasible due to poor compliance.

### Conclusion

Preliminary results suggest the research methods are feasible. Future study using these outcomes and study design is warranted.

**Pyridinium-N-phenolates as molecular probes of serially diluted and agitated solutions: preliminary results**

Dr Steven Cartwright PhD.

A systematic approach to the design of a simple, chemical system for investigating the fundamental nature of homeopathic medicines has led to an experimental protocol for the use of solvatochromic pyridinium-N-phenolate dyes as molecular probes of serially diluted and agitated solutions. Preliminary results using this molecular probe technology indicate that homeopathic potencies appear to increase the affinity of certain cations for the phenoxide moiety of one particular dye, ET30, and that this activity is most easily seen under non-equilibrium conditions.

Evidence will be presented which suggests the homeopathic stimulus is primarily carried not by water, but by ions in solution, together with silanol groups on quartz surfaces of the cuvettes used for assays.

The implications of these results, together with future directions for research in this field, will be discussed.

**Use and knowledge of homeopathic drugs by the general population in Spain**

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**Introduction:** Anxiety disorders (AD) have become the most prevalent psychiatric disorders in the general population and the number of cases coming to the primary care physician is increasing in recent years. This study aims to determine the clinical-epidemiological profile of these patients and to know the true of their management in the Primary Care setting as well as the impact of the different treatments on their short-term evolution.

**Materials and Methods:** Epidemiological survey completed by 15 investigators in the Primary Care setting who had declared to be familiarized with homeopathic drugs, with a total of 110 recruited patients followed in three scheduled visits during 60 days of follow-up. The following data were collected from patients: clinical-epidemiological data, history of AD, information on pharmacological and adjuvant treatments, assessment of the level of anxiety (Hamilton-HAM anxiety scale), the anxiety status perceived by the patient (Visual Analogue Scale - VAS) and evolution of the general state of well-being (using the Clinical Global Impression Scale - CGIC).

**Results:** The mean age of the population studied was 42.5 years (n = 108) and 70% were female. Thirty seven percent (37%) of patients presented a first-degree family history of AD. The most frequent AD were, generalized anxiety disorder (32.7%) and panic disorder (30%). Psychological comorbidity in AD fluctuates from the initial 19% to 38.9% in the bimonthly assessment, being the most frequent association the generalized anxiety disorder with the panic disorder. The use of combination treatments was predominant over monotherapy and the most frequent combination (27.3%) was selective serotonin reuptake inhibitors (SSRI) in combination with benzodiazepine (BZD) and Sedatif-PC (SPC), the most common homeopathic treatment. Homeopathy was used by 74.5% of patients and 50% used other adjuvant treatments. Compliance was highest in the SPC group with only 1 discontinuation due to adverse effects. The administration of treatment caused an improvement in CGI-C in all groups studied that increased after 2 months follow-up.

**Conclusions:** AD affects women more frequently than men and prevalence rates are high in midlife and in subjects with a first degree family history of AD. Psychological comorbidities among these disorders are frequent and increase with time, being generalized anxiety disorder and panic disorder the main reasons for consultation in the Primary care setting. The most frequently used pharmacological treatment is the combination of SSRI + Benzodiazepines + SPC. A quarter of the patients used other adjuvant treatments and half of them used other therapies. Overall clinical evolution was favourable for the patients under any of the treatments. SPC showed an excellent adherence to treatment due to a good safety profile and they have presented a favourable clinical evolution as a monotherapy or in combination, so Sedatif-PC could be an interesting treatment option for the patients with anxiety disorders.

**Effects of homeopathic treatments on the cellular metabolism of wheat: validation of microarrays data by quantitative real-time PCR (qPCR)**

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Plant-based models appear to be an useful approach for basic research in homeopathy in order to fill gaps concerning theoretical models and scientific basis. Such models make it possible to overcome some of the inconveniences of clinical trials for instance placebo effect, ethical issues, duration and high costs; moreover they constitute a vast and cheap source of biological material, essential to perform a large number of experimental repetition (Betti et al., 2009).

The main objective of the research was to give novel insights on the not yet clarified mode of action of homeopathic treatments and to provide reliable information on their efficacy.

The plant-based model considered was the “wheat growth model” (Betti et al., 1997, 2010; Brizzi et al., 2005). A total of 560 common wheat (*Triticum aestivum* L.) seeds were used to carry out the study; part of the seeds were stressed with As<sub>2</sub>O<sub>3</sub> 0.1% to reduce germination and amplify the effect of homeopathic treatment (Brizzi et al., 2011). The seeds were been equally subdivided into four experimental groups: control (non-stressed seeds grown in distilled water); treated control (non-stressed seeds grown in As<sub>2</sub>O<sub>3</sub> 45x); poisoned (stressed seeds grown in distilled water); poisoned-treated (stressed seeds grown in As<sub>2</sub>O<sub>3</sub> 45x). After 7 days of incubation seedlings were collected for molecular analysis. Total RNA isolated from seedling samples were used for microarray analysis in order to study changes in gene expression over different treatments. Subsequently, statistical and bioinformatic analyses were performed to classify genes in “induced” or “repressed” and to assign them a supposed function. Comparative analyses highlighted the particular effect of As<sub>2</sub>O<sub>3</sub> 45x in stressed seeds. Real time PCR was performed to validate gene expression profiles: data obtained with microarray and real time PCR were found to be well correlated.

This research provided novel insights on the mode of action of homeopathic potencies and constitute an important breakthrough in the study of the molecular responses triggered in wheat by ultra-high diluted treatments.

### Acknowledgements

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**References:** Available on request

**Sensitivity and likelihood ratio of symptoms in patients with good therapeutic response to Lycopodium, compared to patients with good response to treatment with other homeopathic medicines. Retrospective study**

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**Background and aims:** Availability of reliable guiding symptoms in order to accurately prescribe homeopathic medicines is a matter of critical importance. Recent published work by ALB Rutten has highlighted the likelihood ratio (LR) of symptoms as an objective manner of addressing the question. The aim of the present study is to establish the sensitivity and LR of 35 common symptoms attributed to Lycopodium, comparing good respondents to this medicine to good respondents to other medicines.

**Methods:** In order to select which symptoms to be evaluated, a survey was conducted with 110 homeopaths -47 from Argentina and 63 from other countries- inquiring on the 10 most important symptoms they use to prescribe Lycopodium in their clinical practice. In a second phase of the study, the presence of selected symptoms was retrospectively assessed in the clinical records of the first visit of patients to the Homeopathic Outpatient Clinic of the Faculty of Medicine of Maimónides University (Buenos Aires). Patients with one only visit, no homeopathic prescription or more than one prescription, less than 18 or more than 65 years old or acute complaints were excluded. Only patients with good response attributable to the homeopathic treatment were included for analysis. Sensitivity (S) -or prevalence in Lycopodium responding cases- Likelihood Ratio (LR) and their 95% Confidence Intervals were calculated for each symptom.

**Results:** Twenty five homeopaths answered the survey and 35 symptoms were selected for the study. 875 records were assessed -about one fourth or the archive- and 564 excluded for different reasons. Of the remaining 311, 76.6% were females and 28.6% were prescribed Lycopodium. Females were more frequently prescribed Lycopodium than males (32.8% vs. 15.1%, P 0.003). Good response was seen more frequently in Lycopodium cases than in other medicines cases (75% vs. 62%, P <0.027). 205 good responding cases were included for symptoms analysis. LR of symptoms' prevalence were calculated between Lycopodium (n=67) and other medicines (n=138) good responding cases.

A group of symptoms emerged as being important pointers to Lycopodium prescription, having high sensitivity and higher than 1 statistically significant LR: *anger from (or intolerant of) contradiction* (S 50.7%, LR 2.7), *dictatorial* (S 40.3%, LR 7.9), *lack of self-confidence* (S 32.8%, LR 3.2), *irritability on waking* (S 20.9%, LR 4.1), *irritability before menses* (S 28.2%, LR 3.9), *helplessness* (S 20.9%, LR 2.2), *haughty* (S 10.4%, LR 4.8), *anticipation* (S 31.3%, LR 2.1), *conscientious* (S 32.8%, LR 1.6), *desire of chocolate* (S 22.4%, LR 2.1), *desire of sweets* (S 46.3%, LR 1.6) and *abdominal distention after eating* (S 34.3%, LR 2.2). The symptom *contemptuous* had a sensitivity of 7.5%, and it was only found in Lycopodium cases.

A second group of symptoms had a sensitivity between 3 and 12% and LR higher than 1, but statistically non significant: *reproaches, egotism, contrary, critical, fear of failure, suspicious, constipation alternating with diarrhoea, lack of vital heat and sensitive to clothing in abdomen*. A third group of symptoms had very low sensitivity (S 1.5): *flatterer, hurry, nose obstruction during night, aversion to onions, past or present gallstones and sleeps on abdomen*. Two symptoms had good sensitivity but LR lower than one, though statistically non significant, probably indicating a contraindication of Lycopodium to be confirmed with further research: *reserved* (S 11.9%, LR 0.7) and *desire for open air* (S 7.5%, LR 0.4). Finally five symptoms were not recorded in Lycopodium cases but in one or two of the other medicines cases: *contemptuous -hard with subordinates and agreeable to superiors-, past or present renal calculi, fear of narrow places, easy satiety and worse at 4 pm*.

**Conclusions:** Retrospective asses of symptoms' sensitivity and LR could have an important place before performing more accurate prospective research about the same matter.

## Highland amphibians and extremely diluted thyroxine

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*Introduction:* After more than two decades of experimental work on a model with amphibians and extremely diluted thyroxine, we now can refer to an independent metaanalysis by B. Harrer from Berlin on the international replication record of that model (Homeopathy 2013; 102: 25-30). A detailed account of the difficulties of this line of research has been published previously. One experiment found to be reproducible both by ourselves (i.e. the initial team) and by independent researchers inquires into the effect of thyroxine (T30x) (an ultra-high dilution obtained by 30 successive steps of tenfold dilution according to instructions of homeopathy) v analogously prepared water (W30x) in amphibians from *highland* biotopes. The purpose of Harrer's study was to replicate this experiment and to perform a metaanalysis reanalyzing the results reported by the initial team and by the independent researchers between 1991 and 2012.

*Methods:* (A): The experiment was replicated by Harrer himself. *Rana temporaria* were taken from an alpine biotope and were treated with T30x or W30x from the 2-legged stage on by adding 3microL of probe dilutions per animal to the basin water at intervals of 48h. Two end-points were considered: first, entry into the 4-legged stage, and second, tail reduction. The experiment was performed blind.

(B): A reanalysis was performed of the results reported by the initial team (based at that time at Graz University and the Graz Boltzmann Institute) and the independent researchers including Harrer himself (R. van Wijk from Utrecht University, H. Lassnig from the Federal Institute of Veterinary Medical Investigation Graz, C. Zausner-Lukitsch from Vienna University, G. Bach, at the suggestion of KIKOM, Bern University, Harrer from Patienteninformation fuer Naturheilkunde Berlin).

*Results:* (A) As in previous experiments, a clear trend was found of T30x animals developing more slowly (i.e. up to 6 h within 3 days) than W30x animals. Due to the small number of animals, the differences were not statistically significant ( $p > 0.05$ ). The effect size, however, was large ( $d > 0.08$ ).

(B) A total of 22 experiments were performed between 1991 and 2012, 15 by the initial team and 7 by altogether 5 independent researchers. In most of these experiments (the sole exception being two performed and reported by ourselves) a trend was found of T30x-animals being slower than W30x-animals. The differences in the individual sub-experiments, each involving 60–100 animals per group, were mostly not statistically significant ( $p > 0.05$ ). The pooled results of the initial team and those

of the independent researchers did show significant differences ( $p < 0.01$  in either case). Pooled T30x values obtained by the initial team were 10.1% smaller than W30x values (100%) ( $p < 0.01$  and  $d > 0.08$ ), and pooled T30x values from the 5 independent researchers were 12.4% smaller ( $p < 0.01$  and  $d > 0.08$ ). Analogously, the number of animals entering the juvenile stage with reduced tail was smaller for T30x than for W30x.

*Conclusion:* A metamorphosis hormone diluted beyond Avogadro's limit using a process derived from homeopathy produced a clear trend of metamorphosis inhibition. This was observed by 7 researchers from Austria, Germany, Switzerland and the Netherlands.

## **Amelioration of pain and distress in tail-ringed lambs using homeopathy**

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**Introduction:** To reduce the incidence of blowfly strike in dirty fleece, lowland lambs in England usually have their tails docked at between 1 and 7 days old. A small and very tight rubber ring is applied to the tail 35 to 50 mm from the base of the tail, thereby constricting the blood supply. The distal part of the tail falls off 2 or 3 weeks afterwards. Whilst it is in the long term welfare interests of the sheep, this routine operation results in short term pain and discomfort for between 15 and 30 minutes. This experiment was conducted to see if homeopathy could be used to ameliorate the discomfort.

**Methods:** This triple blind controlled trial randomised 54 Dorset Down lambs into equal groups of both sexes. The verum group received a homeopathic complex of Aconite, Arnica and Hypericum, all at 200c, administered by mouth from a further diluted preparation in a spray bottle. The placebo group received an apparently similar preparation.

The behaviour of each lamb was recorded on a standardised form, every minute for 20 minutes. Every movement was categorised and counted using check marks, each time that type of movement occurred in each minute.

At the end of the study, the recording sheets were transferred onto a spreadsheet via a scoring system of 0 to 3, where 0 is “no stress” and 3 is “maximum stress”. For example, standing, or lying down with head up would score 0 for “no stress”; whilst lying down on its side and thrashing all four legs would score 3 for “maximum stress”. Other categories of movement scored intermediate values.

**Results:** The spreadsheet for each lamb was scored for each movement and each minute. The scores for each minute were then totalled to give a score for the whole 20 minutes of study, to give the Area Under the Curve. This is an assessment of the total distress experienced by each of the lambs under study.

Frequency histograms were plotted for both groups; mean AUC scores for the verum group were 228.3 and for the placebo group were 320.7; giving an effect size score of 92.4 (c.i. 66.15 to 118.65;  $P < 0.001$ ). This amounts to a reduction in distress (reduced score) of 29% for the verum group.

Mean Distress Scores for each minute were also plotted for both groups. The peak distress for the verum lambs occurred about 3 minutes earlier than the placebo lambs and was 28% lower than the peak score for the placebo group. At the end of the 20 minute recording period, the final distress scores for the verum group were about 35% lower than the placebo group.

**Conclusions:** A reduction of approximately one third in total distress was achieved using homeopathic Aconite, Arnica and Hypericum 200c and is a practical and cost effective means of improving animal welfare on the farm.

**Is Homeopathic treatment as an effective intervention for children with a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD)?**

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How to demonstrate Homeopathic effectiveness is an ongoing question. Pragmatic trials have high external validity, representing homeopathic treatment as it is practised in real life, and may provide a solution. Two studies provide examples. A consecutive case series investigated whether homeopathic treatment is effective for children with ADHD. Twenty children received adjunctive homeopathic treatment and were compared with ten children not receiving homeopathic treatment at baseline and after 24 weeks, on DSMIV characteristics (Conner's Parent Rating Scale - CPRS) and a self-selected-item scale (Measure Your Own Medical Outcome Profile - MYMOP).

An analysis of variance (ANOVA) found a significant interaction between time and the treatment received. A long term analysis of treated children after one year found that they continued to improve, with half the participants registering improvement in their DSMIV scores of over 10 points. Different methodologies were explored to ascertain optimum treatment protocols, and CEASE methodology (Smits 2010) proved especially effective for these children. It was found that remedies often needed repeating to retain effectiveness. This suggested obstacles to cure. CEASE proved effective at removing obstacles after which constitutional remedies needed repeating less often, and their effectiveness was enhanced. Despite the small sample size, this study suggests that homeopathic treatment is an effective intervention for children with ADHD. However limitations such as lack of randomisation, blinding and unequal sample sizes mean results have limited generalisability.

A Pragmatic Randomised Controlled Clinical Trial is being designed to enhance and develop the findings of the above Case Series and provide more powerful and robust evidence. The aim of the trial is to evaluate the comparative clinical and cost effectiveness of adjunctive treatment provided by homeopaths for children with a diagnosis of ADHD, in comparison to standard care alone.

Key elements of the design include the retention of the totality of homeopathic treatment; a control group receiving standard care; equal sample sizes of adequate power; random distribution of groups; groups representative of the ADHD population; homeopathic treatment undertaken by several homeopaths in several locations; evaluation of clinical and cost effectiveness using appropriate outcome measurements reflecting the requirements of stakeholders; and allowance of sufficient trial time to detect results. These studies into homeopathic effectiveness for ADHD are the first pragmatic studies comparing the totality of the homeopathic intervention with usual care. They build on the work of Frei (2005) and Lamont (1997) who demonstrated the effectiveness of Homeopathic remedies for children with ADHD; Jacobs (2005) who demonstrated the effectiveness of remedies and the clinical intervention. A systematic review (Coulter and Dean 2006) recommended studies of 'homeopathy as it is practised by homeopaths ie pragmatic trials. References available on request.

**Dr Peter Fisher** Fri 31 May, 9.30

**Cutting edge to clinical effectiveness: the implications of recent theoretical and research findings in homeopathy**

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Much recent progress in research in homeopathy has been at polar ends of the spectrum: in theory and basic science and clinical effectiveness studies. I will review the implications for research in homeopathy.

'Weak quantum theory' hypotheses for homeopathy have been proposed by Walach and Milgrom. These hypothesise nonlocal action and 'entanglement' so that treatment effects occur in both treatment and control groups in randomised controlled trials (RCTs). These hypotheses have been criticised for not suggesting an experimental test. Beauvais has applied a quantum-like statistical model to RCTs of homeopathy. This gives rise to a remarkable prediction: that the difference between between placebo and homeopathy groups vanishes in centralized blind trials due to 'smearing' (effects of homeopathy occurring in the placebo group). This could be overcome by *in situ* randomization/unblinding: the observables are measured and all operations from randomization to unblinding are performed locally in a defined order, without central supervision. Similarly Almirantis notes that if non-local factors are involved, there will be resistance to reproducibility, so effect sizes will be larger if control treatments were randomly selected homeopathic medicines, rather than blank, since this introduces uncertainty. These theories are testable and have important practical implications if verified.

Recent empirical findings in basic science include evidence on the role of nanoparticles of original substances, silica and gas. Bell's NPCAS model hypothesises that homeopathic medicines consist of nanoparticles, low level stressors cross-adapted to allostatic overload (allostasis is the physiological process of restoring homeostasis, allostatic overload occurs when these mechanisms are overwhelmed). Implications for research include that outcomes should be multivariate and measured over time. These predictions are congruent with those made by nonlocal theories.

Nonlocal theories have not been tested, let alone verified. There are alternative explanations for the alleged lack of positive findings in RCTs of homeopathy. These include that there is nothing to explain. The results of meta-analyses are disputed and, as Mathie et al's recent bibliometric study showed, the literature has not been adequately searched: 30 eligible RCTs not listed by previous meta-analyses were found. Another possible explanation for false-negative results is the quality of homeopathy. Mathie has led the development of a method to evaluate the model validity of homeopathy in clinical trials.

There is a growing number of veterinary RCTs and animal experiments of relatively simple design with positive results. These include replication of the effects of highly dilute thyroxine on amphibian metamorphosis, nosodes for diarrhoea in piglets and an homeopathic complex in fish farming. These seem not to be in line with nonlocal hypotheses.

EPI-3 is a large scale comparative effectiveness study comparing GPs using homeopathy, mixed practice and conventional medicine in France. Upper respiratory tract infections, sleep disorders, anxiety and depression and musculoskeletal disorders were studied in terms of clinical benefit, medical care and medication consumption, adverse effects and loss of therapeutic opportunity. Patients seeking treatment from homeopathic GPs were similar to those attending conventional physicians. Homeopathy had advantages in at least one domain for each disease category.

**Dr Yakov Freed**

Sat 1 June, 15.00

**Bridging the gap between the homeopathic world and the conservative medical world – Test case in rats**

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Sleep is an essential physiological process that underlies crucial cognitive functions as well as emotional reactivity. Thus, Sleep Deprivation (SD) may exert various deleterious effects.

In this study, we aimed to examine the adverse behavioral and hormonal effects of SD and a potential treatment with *Cocculusindicus* 30c (cocc 30C) – a homeopathic remedy.

SD was induced by using the Multiple Platform Method for 48 hours. The effects of SD were evaluated behaviorally (Pre-pulse inhibition, startle response, plus-maze and rotor-rod) at baseline as well as at 6, 12, 24 hours, and 14 days post deprivation. Cocc 30C treatment was administrated Per Os every three hours starting immediately after baseline tests and for a period of 24 hours. On day 14, blood samples were taken and serum levels of corticosterone, testosterone, serotonin and leptin were tested. We found that cocc 30C improved Pre-pulse inhibition 12 and 24 hours post deprivation. Likewise, cocc30C improved motor learning independently from locomotor activity. On day 14 though no behavioral effects were observed, SD led to increased levels of corticosterone and serotonin while decreasing testosterone and leptin. Interestingly, cocc 30C treatment has moderated these hormonal alterations. We conclude that the treatment with cocc 30C recovers both short-term behavioral and the long-term hormonal modulations following SD.

**Harnessing the unmined data rich resources of homeopathic provings: an overview of replicated provings, creating a common language and a method forward**

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Generally conducted by homeopathy practitioners and advocates, rather than scientists, the emphasis of provings has always focused on determining accurate symptom profiles. These are then applied homeopathically in clinical practice, according to the law of similars. But serious questions need to be asked about the quality of provings and the symptom profiles they produce – lack of reproducibility, and inconsistencies in approach and method remaining an issue for 19<sup>th</sup>, 20<sup>th</sup> and 21<sup>st</sup> century provings.

For the vast majority of these experiments the fundamental hypothesis has been, ‘what symptoms and conditions might this substance be useful for?’ But what about re-provings? Repeated improved provings with better design, ethics approval and method have subsequently been conducted on substances from *Chamomilla*, *Tuberculinum* and *Blatta orientalis* to *Kangaroos Milk*.

Comparative evaluation of the data extracted from old and modern provings can reveal identifiable similarities. For example, an overlap of symptoms from a proving of *Culex* was noted compared to a previous one. Conducted in 2004 with sound design and method, the data is compared to a proving of *Culex* conducted in the 1800’s, more than 100 years apart.

In this presentation I will explore a method for comparing subjective symptoms from provings, which if robust enough, challenges the idea that homeopathic responses are placebo.

Four key points will be explored:

1. The findings of these trials are examined and analyzed, discussing the implications for homeopathy as a whole. How is it possible that a homeopathic preparation, often dismissed as placebo, can create a mirror of similar symptoms, especially conducted after such a passage of time? Further, how can placebo create clear affinities with clusters of symptoms in specific locations?
2. The inherent difficulties in comparing symptoms between trials. How can accurate comparisons be made when a symptom is not a simple objective number per se, but rather a description of an experience by a healthy person involved in the trial? This paper suggests a method and design which addresses these challenges as we move forward.

3. The challenges confronting scientists faced with poor proving protocols from the body of homeopathic literature. A new model of conducting provings is proposed to directly address the contention that homeopathy is a placebo response.
4. The direction for how further studies can be conducted to ensure reliable data. In terms of design there are a number of variables at play – the quality of the trial, ethics, inclusion and exclusion criteria, randomisation, control, information on the relative health of provers and the method of extraction of reliable symptoms. All need to be considered to ensure that provings meet the expectations of clinicians, academics and scientists.

## Comparative study of two bioassays with weakened duckweed and yeast treated with homeopathic preparations

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In homeopathic basic research, the question as to the most adequate test systems and apt methodology is still open.

This investigation examined the hypothesis that more complex organisms show stronger reactions to homeopathic remedies than less complex ones.

We compared two Arsenic (As<sup>5+</sup>) stressed bioassays with duckweed (*Lemna gibba*, a multi-cellular autotrophic organism) and yeast (*Saccharomyces cerevisiae*, a single-cellular heterotrophic organism) regarding their response to homeopathic preparations [1].

For duckweed, growth rates of leaf area and leaf number were evaluated. For yeast, growth kinetics were determined by measuring slope, yield and Et<sub>50</sub> (point in time when yield was half maximum) of the sigmoid growth curve. The experiments with duckweed and yeast were performed in parallel (same day, same location and identical homeopathic preparations).

After screening 17 substances, three homeopathic preparations (*Arsenicum album*, *nosode*, *gibberellic acid*) were chosen for repeated experimental series [2]. Five independent experiments were conducted for each remedy with both organisms in parallel. Potency levels used were in the range of 17x–33x for duckweed and 17x–30x for yeast. To control for test system stability, systematic negative control experiments were conducted over the complete experimentation period. All experiments were blinded and randomized.

The systematic negative control experiments did not yield any significant effects. Application of potentized *Arsenicum album* in the duckweed bioassay yielded the largest effects compared to water controls without remedies for the parameters leaf area and leaf number ( $p < 0.001$ ) [1, 3]. Potentized *nosode* preparations also had significant effects on duckweed's leaf area and leaf number ( $p < 0.01$ ). Growth was enhanced across all potency levels. In the yeast system the three homeopathic remedies did not show any significant effects on any growth curve parameter. The results obtained are in line with the hypothesis, that more complex organisms show

stronger reactions to homeopathic remedies than less complex organisms. The test system with *Lemna gibba*, the stressor arsenic ( $As^{5+}$ ) and the homeopathic preparation *Arsenicum album* is suitable to further investigate factors influencing the quality and effects of potentized substances [4].

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**Effectiveness of complex homeopathic medicinal products in the treatment of children with painful teething**

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**Background:**

Complex homeopathic medicinal products are sold over the counter for self-limiting diseases in children such as painful teething. The possible effectiveness of these complex products is predominantly based on the clinical experience with each of the individual homeopathic active substances in the product. So far, only a few clinical studies in children have been performed to investigate the effectiveness of complex homeopathic products as a whole.

**Objective:**

To investigate the comparative effectiveness and tolerability of two complex homeopathic medicinal products, Dentokind versus Viburcol, in the treatment of children with painful teething.

**Design:**

A multicentre, randomized comparative clinical study with two parallel groups. One group received Dentokind (tablets), containing five homeopathic active substances: Belladonna D6, Chamomilla D6, Ferrum Phosphoricum D6, Hepar sulfuris D12 and Pulsatilla D6. The other group received Viburcol (suppositories), containing six homeopathic active substances: Chamomilla D1, Belladonna D2, Solanum D4, Plantago D3, Pulsatilla D3 and Calcium Carbonicum D8. Children in the age of  $\leq 6$  years with symptoms of painful dentation were included in the study. Exclusion criteria were fever of  $\geq 38$  °C, severe comorbidity and/or oncological diseases. The main outcome parameter was total scores of subjective complaints and clinical symptoms as assessed by parents and physicians after 3 and 7 days of treatment. Other outcome parameters were parent satisfaction and the number of reported adverse events.

**Results and Conclusions:**

At (outpatient) paediatric clinics in Russia, 200 children with symptoms of painful teething were included in the study, 100 in the Dentokind group and another 100 children in the Viburcol group. Demographics and outcome data are currently being analysed. Results and conclusions will be therefore be presented at the conference.

**The influence of Aconitum Napellus versus placebo on anxiety and salivary cortisol, in stress induced by intense and short term physical effort**

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Background. Intense and short term physical effort is a stress factor for sedentary persons. The correctly chosen homeopathic remedy, in other words the simillimum, modulates physical, emotional and mental level of the person to whom it was given, therefore also the psycho-emotional state stress-induced. Aconitum Napellus (AN) is characterized by a state of anxiety, anguish of mind and body, fear, physical and mental restlessness.

Aims. The objective of the study is to highlight the AN influence on the dynamic of two parameters, anxiety and salivary cortisol, in peri-stress changes induced by intense and short term physical effort, on sedentary subjects.

Methods. All chosen subjects (n = 30) had AN recommendation and had voluntary participated, according to the requirements of the study. Stress was represented by an intense and short term physical effort, made with a Monark Ergomedic 839E cycle ergometer. Three groups of subjects were selected, the first, the control group (C), who was not given anything; the second, who received placebo (P); and the third who received AN. Test was made the day after taking P and AN. Analyzed indicators were anxiety and salivary cortisol. Statistical evaluation was made on the basis of Student test.

Results. Although the values for anxiety and salivary cortisol were slightly higher on C compared with P, differences between them were not significant. At all peri-stress times, anxiety and salivary cortisol values in C and P were higher than in AN, significant differences being: immediately pre-stress for anxiety; immediately pre-stress and immediately post-stress for salivary cortisol.

Conclusions. 1) Influence on anxiety and salivary cortisol was significantly more intense in AN compared to P. 2) Under AN influence, anxiety and salivary cortisol were significantly reduced immediately pre- and post effort. 3) AN significantly influenced more anxiety than salivary cortisol, immediately pre- and post-stress times. 4) AN may be an effective, safe and accessible modulation path for stress caused by intense and short term physical effort, on AN constitutional sedentary persons.

**Key words:** stress, homeopathy, Aconitum Napellus remedy, anxiety, salivary cortisol, short term physical effort

**Towards an evidence-based homeopathic treatment for PMS**

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**Objective**

Homeopathy could offer safe and effective treatment for women with premenstrual syndrome/symptoms (PMS/S). A research program on effectiveness and efficacy was initiated to evaluate a semi-standardised individualised homeopathic treatment of women with PMS/S.

**Methods/Results**

The first step of our research program was to standardise individualised homeopathic treatment, to facilitate clinical research. Therefore, a semi-standardised computerised algorithm was developed and validated for homeopathic treatment of women with PMS/S with 11 medicines. A questionnaire was used to collect the women's keynote symptoms and characteristics for the 11 medicines. The first homeopathic prescription had to be according to the algorithm outcome. At follow-up, the prescription could be changed according to the analysis of the doctor. This semi-standardisation of the treatment minimised variability in prescription between the participating doctors, enabled optimum reproducibility of the treatment, yet respected the individualised approach.

Secondly, the use of this algorithm was evaluated in Dutch homeopathic practice in 38 women with 3 months follow-up (Klein-Laansma et al, 2010). In an extension of this feasibility study, with 9 months follow-up and in a sample of 77 women suffering from PMS/S, we further evaluated the utility of the semi-standardised algorithm, measured changes in premenstrual symptom scores and detected possible predictive characteristics. This research was conducted in practices of 20 homeopathic doctors in the Netherlands between 2007-2011. Recruitment in this study proved difficult and the dropout rate was considerable. The algorithm proved useful and effective in daily homeopathic practice. We detected a significant decline in mean PMS-symptom scores over time, especially in women with moderate to severe PMS.

Next, in October 2012 we started an international pragmatic trial to evaluate the feasibility of a larger trial to establish the added value of this homeopathic treatment compared with usual care only. This project is a collaboration between research groups at the Louis Bolk Institute, Driebergen, the Netherlands, the Mid-Sweden University, Sundsvall, Sweden and the Women's Hospital, University of Heidelberg, Germany. Previously, a double blind randomised placebo controlled pilot study was conducted in Israel on individualised homeopathic treatment for PMS with 5 homeopathic medicines (Yakir et al, 2001). This study was replicated with 96 women and 14 homeopathic medicines, (Yakir, thesis, 2002). In both studies, the homeopathic treatment proved

superior to placebo, with significant results. For the homeopathic medicine selection, the 'symptom-cluster' approach was used: women first completed a questionnaire with symptoms representing keynotes of the homeopathic medicines. Women, whose symptom cluster matched the remedy picture of one of the homeopathic medicines were included in the trial. Other women were assigned to a parallel trial.

## **Conclusions**

So far, positive clinical data have been obtained for the effectiveness and efficacy of homeopathic treatment in PMS. This line of research can act as an example on how to build up evidence for individualised homeopathic treatment in specific clinical conditions.

**Treatment of nervous complaints and exhaustion with the homeopathic medicinal product Manuia® - Results of a cohort study**Wilkens J<sup>1</sup>, Klement P<sup>2</sup>*1 Humboldt Clinic, Bad Steben, Germany**2 Deutsche Homöopathie-Union, Karlsruhe, Germany*

**Background:** Exhaustion, nervousness and decreased physical and mental capability are recurrent challenges in GPs' daily routine. They are often resulting from overexertion, or disturbed sleep. Nowadays people feel exhausted and weak due to continuously increasing professional demands and rising challenges in daily life. The approved homeopathic medicinal product Manuia is used in the mentioned therapeutic area. It contains four single active substances: Damiana, Panax ginseng, Acidum phosphoricum and Ambra. So far, effectiveness and tolerability was confirmed by clinical experience, but systematically collected data were lacking.

**Patients and Methods:** Between January and June 2011 the clinical effectiveness and tolerability of Manuia was systematically investigated in a prospective, multicentre, non-interventional cohort study. A total of 420 patients were observed by 76 German physicians in private practices. Median observation period was 24 days, median duration of symptoms since diagnosis 5 months.

As main outcome measure severity course of 20 symptoms (nervousness, irritability, sleep disturbances, hyperactivity, impaired concentration, listlessness, frustration, moroseness, exhaustion, dispiritedness, decreased capability, feeling of heteronomy, feeling lonely, feeling pressure to perform, feeling excessive demands, forgetfulness, gastrointestinal complaints, cardiovascular complaints, muscle tension, headache) was evaluated with a 5-item score (0=not present; 4=very severe). In addition physicians' Clinical Global Impression (CGI), patients' quality of life and ability to actively attend different domains of daily's life, and tolerability of Manuia were documented.

**Results:** The sum score as well as the severity of each single symptom decreased significantly during the observations' period ( $p < 0.01$ , paired t-test). Illness severity measured by CGI decreased significantly ( $p < 0.01$ , McNemar test; CGI 4-7: 71.7% to 35.2%). Ability to work and to attend social and family life improved significantly ( $p < 0.01$ , McNemar test). In 77.1% ( $n=324$  out of 420) of the patients quality of life was good, very good or excellent during control visit, compared to 15.8% ( $n=66$  out of 420) at baseline. 92.4% of the patients rated their condition as improved, 64.1% as much or very much improved. Median duration until onset of action was 7 days. Tolerability was good or very good in 98.1% of all cases.

**Conclusion**

The study data underlined the existing good clinical experience with Manuia and suggests Manuia as a therapeutic option in the treatment of nervous complaints and exhaustion. Further controlled studies are necessary to confirm these findings.

**Might evaporation-induced droplet patterns serve in agro-homeopathic research and support experimental trials?**Maria Olga Kokornaczyk<sup>1\*</sup>, Giovanni Dinelli<sup>1</sup>, Lucietta Betti<sup>1</sup><sup>1</sup> Department of Agricultural Sciences, University of Bologna, Viale Fanin 42, 40127 Bologna, Italy

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Agro-homeopathy provides numerous solutions for a sustainable agricultural production, like for instance cost-saving and residue-free treatments for yield improvement and management of diseases and pests. However, one of the main difficulties in this approach is the right treatment choice (i.e. the curative principle and its dilution level) that often requires numerous time & cost consuming experimental trials.

In the present experiment we applied the droplet evaporation method, previously developed by our research team for wheat quality analysis [1], to test the influence of highly diluted homeopathic treatments (HD) of *Arsenicum album* on both healthy and previously arsenic trioxide stressed wheat seeds (isopathic model) [2]. The pattern evaluation of the resulting polycrystalline structures consisted in (i) the calculation of their local connected fractal dimension, known to reflect the pattern complexity, and (ii) in the fluctuating asymmetry measurement, known to be inversely correlated with the symmetry exactness of the structures, and thus also the vitality of the sample [3]. In polycrystalline structures formed under the same conditions these two measurements have been found to reflect the sample health. Additionally, in order to support the crystallographic data with traditional analysis methods for seed viability, we performed the seed germination test and measured the shoot lengths: our results show that the complexity and symmetry of polycrystalline structures correlates with the viability of non-stressed and stressed wheat seeds following *Arsenicum album* HD with respect to control.

These first results indicate that the droplet evaporation method might constitute a support for experimental trials and/or a pre-screening method for treatment test, since it shows to be sensitive to the sample vitality.

**Keywords:** Droplet evaporation method, polycrystalline structures, bilateral symmetry, fractal dimension, arsenic trioxide, ultra high dilutions

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## Model validity of randomised placebo-controlled trials of individualised homeopathic treatment

Robert T Mathie, Michel Van Wassenhoven, Rajkumar K Manchanda, Laurence Terzan, Gilles Chauferin, Flávio Dantas, Jennifer Jacobs, Joyce Frye, Menachem Oberbaum, John A Ives, Helmut Roniger, Peter Fisher  
*British Homeopathic Association, Luton, United Kingdom*

**Purpose:** A new programme of systematic reviews of randomised controlled trials (RCTs) of homeopathy distinguishes several key attributes of study design and quality: placebo controlled *cf.* other-than-placebo controlled; individualised *cf.* non-individualised homeopathy; treatment *cf.* prophylaxis; internal validity *cf.* model validity.<sup>1</sup> The present phase of the review programme focuses on assessing the model validity (MV) of peer-reviewed, placebo-controlled, RCTs of individualised homeopathic treatment

**Methods:** A systematic literature search<sup>1</sup> and subsequent reappraisal of retrieved records identified 31 RCTs that satisfied the inclusion criteria for the present study. MV of the eligible RCTs was appraised using a novel criterion-based method.<sup>2</sup> Assessment domains address: (i) the rationale for the choice of the particular homeopathic intervention; (ii) the homeopathic principles reflected in the intervention; (iii) the extent of homeopathic practitioner input; (iv) the relevance of the main outcome measure; (v) the capability of the main outcome measure to detect change; (vi) the length of follow-up to the endpoint of the study. These six MV domains per RCT were categorised by each of three independent assessors as 'acceptable', 'unclear' or 'unacceptable', disparities of opinion being resolved by consensus discussion.

**Results:** Domain-specific and overall ratings of MV per RCT await the outcome of ongoing consensus discussions. A full set of findings will be presented at conference.

**Conclusions:** MV data contribute importantly to the appraisal of RCT quality in systematic reviews of homeopathy.

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**Study of *Gelsemium sempervirens* in a neurocyte model. An update**Debora Oliosio, Marta Marzotto, Paolo Bellavite

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Previous investigations showed significant anxiolytic-like activities of *Gelsemium sempervirens* L. (*Gelsemium s.*) in mice models. To provide new insights into the neural substrates of anxiety and to identify drug targets, we decided to investigate the *Gelsemium s.* mechanism of action in neuronal models by assessing the genome expression changes. The SH-SY5Y and IMR-32 human neuroblastoma cells were used since are widely employed in neuropharmacology and well characterised. The drugs were produced by Boiron Laboratoires (Lyon), starting from a whole-plant-hydroalcoholic extract and the cells treated with 6 increasing dilutions 2c, 3c, 4c, 5c, 9c, 30c. We compared the drug effects with those of control solutions prepared by the same procedure, but with the solvent vehicle without the plant extract. All dilution steps were followed by strong succussion. Final ethanol concentration was 0.03% v/v. After having ruled out possible toxic effects of any dilution on cell viability, we evaluated gene expression using a microarray designed for the whole human transcriptome. To ensure the most precise and sensitive detection of effects, we performed 7 separate dose-response experiments (4 with SH-SY5Y and 3 with IMR-32 cells) and used two statistical approaches: Limma statistics to select the differentially expressed genes and Friedman test followed by Wilcoxon signed-rank test to check the null hypothesis that high dilutions have no effect in this model. In general, the range of changes in gene expression was quite narrow: in *Gelsemium s.* 2c and 3c only a small subset of genes (577 and 165, respectively) showed mean expression changes > 0.5. Of a total of 45033 transcripts, exposure to 2c dilution promoted a significant down-expression of 49 genes, while 7 genes were slightly overexpressed. No changes of housekeeping genes were recorded. The changes in the 56 selected genes of SH-SY5Y cells were in the same direction in the IMR32 cells, showing that the expression of the same gene set was also modified in a second type of neurocyte, although the most sensitive model for detecting the effect of *Gelsemium s.* is the SH-SY5Y cell line. With higher dilutions, the changes in gene expression were not rated as significant by Limma statistics using p value adjusted <0.05 as cut-off. However, most of the genes downregulated in the 2c-treated samples were also under-expressed in 3c and, to a varying extent, even in higher dilutions. In the Wilcoxon analysis applied to the mean of 4 replicates of 49 downregulated and 7 upregulated genes the number of downregulated ones was systematically higher than the number of genes with positive fold change over all dilutions (p<0.0001). No significant differences between treatments and controls in a randomly chosen gene set of 49 genes were observed, suggesting that the *Gelsemium s.* effects are specific. The main group of functional features includes genes coding for membrane receptors, in particular involved in G-protein coupled transduction systems, in olfactory transduction, calcium signalling, and inflammatory pathways. We are currently verifying this microarray evidence on a group of most expressed genes by real-time PCR.

**In-vitro experiments to investigate the effects of homeopathic drugs for chronic aggressive periodontitis by lymphocyte migration activity**

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**Background:** Several homeopathic drugs are applied in the treatment of periodontal inflammation. However less is know about the basic working principles of highly diluted remedies in such chronic inflammatory conditions. We therefore aimed at investigating the effects of homeopathic drugs in periodontal inflammation by observing lymphocyte migration activity.

**Material and Methods:** Lymphocytes from blood samples of three patients suffering on chronic aggressive periodontitis and three matched healthy volunteers were extracted and embedded in a collage matrix migration assays together with highly diluted (D12 and C200) aquaeous extract from Mercurius solubilis, Silicea, Sulfur, Tuberculinum, or placebo. Activity and speed of lypocytes were observed in a 60 min time frame using flow cytometry. Statistical analysis was performed using univariate statistics and SiZer time series analysis.

**Results:** A significantly reduced migration activity and speed was observed in lymphocytes extracted from the patients suffering on chronic aggressive periodontitis compared to those of healthy volunteers (mean activity: 12.5% vs. 26.3%). While C-potencies did not reveal strong differences between placebo and substances some meaningful effects were observed in D-potencies compared with placebo: moderate but not significant inhibiting effects with regards to activity were observed in lymphocytes treated with Silicea extract (mean activity: 13.3% vs. 11.9% in patients' and 26.2% vs. 22.2% in healthy samples). The strongest and most specific effects were observed in Sulphur D12 which showed an activating effect in lymphocytes of patients (mean activity: 11,1% vs. 23,8%) but not in those of healthy volunteers (25,8% vs. 25,6%). SiZer analysis confirmed this effect to be significant.

**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 and thus proves model validity. Results from our pilot study might encourage further investigations on the role of highly diluted Sulphur in the treatment of periodontitis.

**Topic:** In vitro animal and plant-based research

**Use of Homeopathy for prophylaxis of urinary tract infections in patients with neurogenic bladder dysfunction**

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Background: Patients with neurogenic bladder dysfunction are prone to various urologic disorders which sometimes cannot be appropriately treated. Especially recurrent urinary tract infections (UTI) in patients with spinal cord injury are a frequent clinical problem. Often, conventional preventive measures are not successful. We present our initial results of collaboration between homeopaths and urologists in these patients.

Materials and Methods: after exclusion of morphologic abnormalities and initiation of a standard regime for prophylaxis, all patients with a neurogenic lower urinary tract dysfunction (NLUTD) due to spinal cord injury (SCI) with more than 3 symptomatic UTI/year were offered additional homeopathic care (classical homeopathy with an individualized approach). UTI symptoms were fever, incontinence, increased spasticity, decreased bladder capacity or pain/decreased general health combined with significant bacteriuria.

Results: Five of seven patients opted for homeopathic treatment. The bacterial strains detected in urinalysis were *E. coli*, *proteus mirabilis* and *Klebsiella pneumonia*, respectively. Morphologic and functional reasons for recurrent UTI were excluded by sonography, cystoscopy and urodynamics. After treatment, with a median follow-up of 15 months, 3 of these patients remained free of UTI, whereas UTI frequency was reduced in the other 2 patients. In three patients, standard prophylactic treatment could be reduced. No side effects were encountered.

Conclusion: Our initial experience with homeopathic prevention of UTI is encouraging. Keys for a fruitful cooperation are well-qualified partners, mutual respect and the motivation to cooperate closely. For an evidence-based evaluation of this concept, prospective studies are required.

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**Clinical trial of lipoma**

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**Objective:** This study aimed at evolving a group of useful homoeopathic medicine in the management of Lipomas to identify their reliable indications, most useful potencies, frequency of administration and relationship with other medicines.

**Methods:** This is brief research project on clinical studies on about 106 cases to observe the effects of Homoeopathic medicines on Lipomas. Author studied as Chief Investigator under the Homoeopathic Medical Specialized Clinic, Abu Dhabi, United Arab Emirates. This research project for five years 2005 to 2010. The research work was done on new and old selective cases of outpatient department of Homoeopathic Medical Specialized clinic, Abu Dhabi, United Arab Emirates. The entire study was done in Department of research along with assistance, advice and consultation with other allied doctors in Abu Dhabi, United Arab Emirates. Out of 106 patients, all are males, no female patient were enrolled in the study as per the inclusion criteria. Various specific parameters were followed during improvement.

**Results:** Out of 106 patients followed up, 62 patients were cured, 17 patients showed marked improvement, 13 patients moderate improvement, 8 patients mild improvement and 6 patients dropped out. Nine homoeopathic medicine were found to be useful in the study while *Thuja occidentalis* was the most useful medicine, as it alone improved 42 patients out of 62 patients to whom it was prescribed. Other useful medicine were sulphur (n = 17), *Rhus toxicodendron* (n = 14); *Mercurius solubilis* (n = 9); *Syphilinum* (n = 7), *Pulsatilla* (n = 5); *Calcarea carbonica* (n = 5); *Baryta carb* (n = 4) and *Lycopodium* (n = 3).

**Conclusion:** This clinical trial helped to identify a group of 9 most useful homoeopathic medicines in the management of Lipoma. However a controlled study with definite outcome measures needs to be taken up to make it more evidence based.

## **Homeopathy in the public health system: the experience in Lucca Hospital (1998-2011)**

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The Homeopathic Clinic in Lucca, funded by the Region of Tuscany, was originally set up in 1998 as part of a pilot project designed to evaluate the possibility of including complementary medicine (CM) into the public health care system.

### **The following are the main activities in the clinical field, research and education carried out in these years.**

*Outcome.* The data have been updated with those collected from September 1998 to December 2010: 2,592 patients visited for a total of 6812 consecutive visits. The results were assessed using the Glasgow Homeopathic Hospital Outcome Score (GHHOS).

*Paediatric patients.* An observational longitudinal study was carried out on 551 paediatric patients below or equal to the age of 14 years (mean age 5.9 years), that is 25.7% of 2,141 patients consecutively examined from 1998 to 2008.

*Adverse effects.* In order to assess the possible risk arising from the use of homeopathy a prospective study was carried out to investigate the adverse drug events related to homeopathic medicines. Out of 335 homeopathic consecutive follow-up visits, nine adverse reactions were reported (2.68%).

*Clinical risk management.* A training course for the health professionals of Tuscan public centres of CM., including homeopathy, was conducted. The aim was to develop a plan for the management of clinical risk starting from the analysis of the activities in the clinics of CM, and a systematic approach aiming at identifying and preventing risks.

*Homeopathic aggravation.* To evaluate the type, intensity and frequency of homeopathic aggravation, in particular with Quintamillesimal dilutions (LM or Q), and its prognostic value, a retrospective study was realized on the basis of clinical data. The study examines 1,108 patients consecutively visited, and 441 cases with follow-up. Sixty-three of them (14%) reported a homeopathic aggravation.

*Compliance.* In order to understand why the patients did not return for follow-up consultations (drop-out) a telephone survey was carried out on each patient visited from 6/1, 2002 to 5/31, 2003, who did not return for a follow-up visit. 37 patients out of 73 referred to the effectiveness of the treatment and the improvement in their state of health as the reason why they did not return.

*Long term outcome of atopic patients.* To study the outcome of atopic diseases (AD) in paediatric patients homeopathically treated and the clinical evolution of 213 (38.6%) with atopic diseases out of 551 children consecutively examined from 1998 to 2008. After 5 years from the first visit, all children were contacted for long-term evaluation of the disease.

*Anti-cancer treatment.* An outpatient Clinic of integrative medicine applied to oncology was set up in October 2010. In the preliminary stage of activities, 97 patients were visited, with various types of cancer.

*Cost-benefit evaluation.* A study of the Homeopathic Clinic of Lucca demonstrated cost/effectiveness of homeopathy in respiratory diseases. Cost variation for the specific chemical/therapeutic subgroup recorded a decrease in the first and second year of – 46.29% ( $p < 0.01$ ,  $n = 105$ ) and – 47.45% ( $n = 72$ ) respectively.

**Conclusion.** All these data demonstrate the validity of the integration carried out in Tuscany and the need to strengthen and consolidate the activities of complementary medicine in public healthcare structures.

**Will this medicine work for me? Towards a scientific answer**

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Which answer would you prefer: 1. "This medicine works better than a placebo", or: 2. "I estimate the chance that this medicine will work in your case to be 60%"?

These two answers reflect a two and a half century lasting dispute between two statistical methods, 'classical' (frequentist) and Bayesian. The first is regarded to be more scientific, the latter played a major part in solving many of history's most important problems, like deciphering coded messages in WO II and predicting disasters. Nowadays many computer programs incorporate Bayes' theorem to handle experiential knowledge.

Because RCT evidence does not allow other conclusions, the patient can only expect a yes-or-no statement about efficacy of conventional medicines. But this answer might still be false in his particular case. Other factors, like correct diagnosis, genetic susceptibility and comorbidity, also determine if the medicine works. The diagnostic process preceding the prescription is Bayesian and renders the probability of a specific diagnosis.

Bayesian philosophy is about learning from past experience, e.g. about characteristics of patients responding well to specific medicines. Like a medical diagnosis, the choice of a homeopathic medicine is a Bayesian process. Different personal characteristics add up, stepwise increasing the chance that a specific homeopathic medicine will work.

Hitherto homeopathic doctors have been using Bayesian statistics implicitly: characteristic symptoms pointing towards a specific medicine occur more frequently in patients responding well to that medicine than in patients responding to other medicines. It is a small step to make this rule explicit in various types of research and data collection. All we need to know is the prevalence of a symptom in the population responding well to a specific symptom and in the remainder of the population. The ratio between these two is called the Likelihood Ratio (LR).

The research we need is accepted in conventional diagnosis research. Like all kinds of research we will have to deal with possible bias; like our reference standard: what is a good result? Symptoms should be defined more accurately, etcetera. These problems have been neglected in the past. We must realise that this research is meant to improve homeopathy, not to prove it. However, improved homeopathy will render better proof.

Several methods for Bayesian assessment of symptoms are demonstrated. The most valid and time-consuming method is prospective research of a small set of symptoms, but even with this method we can achieve a tremendous scientific improvement of homeopathy within a limited amount of time. Within ten years we could know LRs of characteristic symptoms for our most frequently prescribed homeopathic medicines. Applying the formula that goes with Bayesian theory we will be able to tell the patient: "Based on the symptoms you gave me I expect the chance that medicine A works for you to be x%".

### **Protocol for prevention and treatment of dengue fever and its complications**

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The dengue virus (DENV) currently infects 50-100 million people per year, causing about 500,000 cases of severe complications (dengue hemorrhagic fever – DHF, and dengue shock syndrome -DSS) and 20-25,000 deaths. All attempts at control of the mosquito vector systematically failed, and there is no specific treatment nor vaccine currently available. [1] Homeopathy has a long record of success in the treatment of epidemic diseases. Recent experiences in Brazil and India strongly point to the possible efficacy of homeopathic prophylaxis and treatment of dengue, at low cost, satisfactory acceptance by the population, and lack of adverse events [2,3]. However, lack of financial support hindered proper collection and reliable statistical analysis of data.

The present is a multicenter study that will be conducted in Brazilian counties where the staff of primary health care services include homeopathic doctors, and exhibit high incidence and prevalence of DENV infection. The first stage of the project will comprise training of the multi-professional staff and preparation of infrastructure to be ready when the first signs of a forthcoming epidemic outbreak appear. Prophylaxis of DENV infection will be performed within the context of a randomized, double-blind placebo controlled clinical trial involving areas exhibiting increase of the number of cases. The first 20 cases will be analyzed by an expert panel to define the homeopathic medication required for preventive purposes, which will be administered to 50% of the exposed population, randomized on a population-basis according to administrative primary health care regions, whereas the other 50% will be given a placebo.

Identified cases of dengue will be included in a separate double-blind placebo-controlled clinical trial, where they will be randomly allocated to homeopathic treatment or placebo. In this instance, each case will be individually assessed by the participating physicians to establish the homeopathic treatment needed. In no case conventional prophylactic measures and medication will be relinquished. The homeopathic drugs in both instances will be selected from electronic databases listing all the available drugs and their symptom-based clinical indications. Where available, medication will be provided by pharmacies belonging to/affiliated with the Brazilian health public system. Otherwise, they will be purchased by the patients, this being a further reason for the present request of funding.

**Outcomes:** 1) Prophylaxis: DENV infection reduction (treatment difference effect size) based on the current diagnostic criteria of DENV infection; 2) risk reduction of the incidence of muscle/joint pain and fever, according to to DAIDS grade scale [4] on day 2 after randomization. **Statistical analysis:** the sample will be described as to primary demographic variables (age, gender, and socioeconomic status). Proportions will be used for categorical variables, and descriptive measures (mean, median, and

standard deviation) for continuous variables. Exploratory bivariate correlations will be tested among the main variables and outcome measures, disregarding the cluster design by using 2 sample independent t-tests (for variables with normal distribution) for continuous variables, and chi-square test (or Fisher exact test in case 20% or more of the table cells exhibit value 5 or lower) for categorical variables. The generalized estimating equation (GEE) approach will be used to construct an extension of standard logistic regression and adjustment for the effect of clustering. Our main analysis will be based on intention-to-treat (ITT) (according to randomization), and secondarily per protocol.

Were the results of the proposed protocol be successful, we intend to: 1) measure the long-term effects of homeopathic prophylaxis of dengue as expectably, reduction in the number of susceptible individuals should reduce the circulation of DENV in the community, and thus reduce the incidence and prevalence of the epidemics; 2) train the homeopaths within the Brazilian public health service in the use of the protocol and system of data generation for application in any forthcoming outbreak; 2) establish a partnership with the Central Council for Research in Homoeopathy, Ministry of Health & Family Welfare, India, for global training in and application of the protocol.

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## Do pathogenetic trials produce consistent and recognisable symptom pictures? Results from a pilot pathogenetic trial study

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**Background:** Pathogenetic trials (provings) are the foundation of homeopathic treatment as they provide the set of symptoms characteristic of a particular homeopathic medicine (commonly referred to as a remedy picture). Homeopaths choose homeopathic medicines by comparing these remedy pictures with the symptoms the patient is presenting. The ability of a homeopathic practitioner to identify a remedy suitable for the patient based on these remedy pictures, underpins the successful clinical practice of homeopathy.

**Objective:** To test whether homeopathic pathogenetic trials generate consistent and recognizable sets of symptoms in consecutive trials.

**Design:** Practising homeopaths were given the set of symptoms generated by a recent pathogenetic trial and asked to identify the homeopathic medicine used.

**Homeopathic trial substance:** Ozone, prepared by homeopathic method to the ultramolecular dilution of 30c (equivalent to a 1 in 1060 dilution), was chosen at random from twenty potential medicines. This medicine was the subject of a pathogenetic trial in 2008 and the resulting remedy picture had been incorporated into the homeopathic literature.

**Results:** When asked to choose three medicines from the total number of possible homeopathic medicines (2372 at the time)<sup>4</sup>, two homeopaths out of the seven selected the correct medicine, corresponding to a statistically very significant result ( $p < 0.0001$ ). Subsequently, when the choice of medicines was restricted to a list of 20, the same two homeopaths selected the correct medicine, however none of the other homeopaths did, resulting in a non-significant result ( $p = 0.2$ ).

**Discussion:** The selection of the correct homeopathic medicine from the unrestricted list ( $n=2372$  medicines) by two homeopaths is noteworthy given that the homeopathic medicine used during the pathogenetic trial was diluted well beyond Avogadro's number and would, as such, not be expected to produce any detectable - let alone recognisable - symptomatology.

**Conclusion:** The results show that practising homeopaths are able to correctly identify a homeopathic medicine from the set of symptoms it generated during a pathogenetic trial ( $p < 0.0001$ ). Furthermore, since recognisable symptoms are produced by taking an ultramolecular homeopathic medicine, this study suggests that the remedy pictures generated during pathogenetic trials are not only non-random, but also specific and consistent over time. Finally, this study validates the methodology of pathogenetic trials for obtaining both a characteristic and consistent set of symptoms. These promising preliminary findings warrant replication. Possible improvements to the trial design were identified and should be incorporated into future studies.

**An open observational study on efficacy of miasmatic prescription in the prevention of Japanese Encephalitis**

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The recurrence, resistance to vaccines and medicines and the rise of infectious diseases is quite alarming in India. One among them is Japanese Encephalitis (J.E.), an endemo-epidemic acute encephalomyelitis accompanying a viral infection. The first case of J.E. was detected in 1979 in Andhra Pradesh state. Initially Belladonna was administered in a small way with good results, but the Government did not take any effective steps. Since 1990 it had become an unmanageable problem. Between 1993 and 1999 recorded J.E. cases were 5308, and 1511 children died. In spite of vaccination it continued unabated. The Government sought the help of homeopaths in combating this epidemic in 1999.

As prophylactic drugs, Belladonna 200 on 1, 2, 3 days one dose each, Calcarea Carb 200 on 10th day and Tuberculinum 10 M on 25th day were administered in a phased manner to all children in the age group of 0-15 years in the month of August every year for three consecutive years. Symptom similarity, complementary relationship, virulence and underlying miasms were taken into consideration while selecting these drugs. This project was named B.C.T. After its commencement in 1999 the mortality and morbidity rates of J.E. fell drastically. 343 cases were reported in 2000 with 72 deaths, in 2001 only 30 cases with 4 deaths, in 2002 only 18 cases but no deaths, in 2003 and 2004 no cases were recorded. The Government had officially published the statistics and acknowledged the efficacy of homeopathy. This is the first major involvement of homeopathy in the field of prevention of epidemic diseases in our country. Neighbouring states which have not adopted this method continued to show higher incidence of J.E. cases. After witnessing the decline in India other nations are showing keen interest in this innovative method. Subsequently the Virologists of the Institute of Tropical Diseases, Kolkata conducted experiments on Belladonna's antiviral effects on Chorionic Allantoic Membrane and ascertained the efficacy of these drugs. The findings were published in American Journal of Infectious Diseases. Endemics and epidemics should be studied from the miasmatic viewpoint to understand their virulence, change of patterns and recurrence. This work has been carried out under the personal supervision of Dr.G.L.N.Sastry.

**Keywords:** Epidemics, homeopathic prophylaxis, Belladonna, Calcarea Carbonica, Tuberculinum.

**The impact in term of public health of the sleep, anxiety and depressive disorders management by physicians prescribing homeopathic medicine in France. The EPI3 programme**

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**Objectives:** This programme reports the results of a cross-sectional study and a one year cohort study on patients seeking treatment for sleep, anxiety and depressive disorders (SADD) from general practitioners(GPs). The **objective** of the cross-sectional study was to describe and compare patients seeking treatment for SADD from GPs who exclusively prescribe conventional medicine (GP-CM), regularly prescribe homeopathy within a mixed practice (GP-Mx), or are certified homeopathic GPs (GP-Ho). The one year cohort study assessed the effect of different prescribing preferences in primary care for homeopathic drugs with reference to conventional psychotropic drugs use, clinical progression and a potential loss of therapeutic opportunity defined by the self-declaration of suicide attempts and injuries between the three groups of patients for anxiety and depressive disorders (ADD)

**Methods:** The study was a nationwide, observational survey of a representative sample of general practitioners and their patients in France. The sampling strategy ensured a sufficient number of GPs in each of the three groups to allow comparison of their patients. Patients completed a questionnaire on socio-demographics, lifestyle and QoL (SF12). Diagnoses and co-morbidities were recorded by the physician. Then, patients with ADD diagnosed by their GP and confirmed by a score  $\geq$  nine at 72 hours in the Hospital Anxiety and Depression Scale (HADS) were included in the cohort. They participated in a standardized telephone interview at inclusion, one, three and twelve months, with the HADS, and detailed medication consumption.

**Results:** 1572 patients diagnosed with SADD by 825 GPs in the cross-sectional study. While patients differed principally in their socio-demographics profiles and conventional psychotropic prescriptions (31.2% GP-Ho vs 64% GP-CM), they were actually rather similar regarding the severity of SADD in terms of comorbidities and QoL. A total of

710 ADD patients were included in the AD cohort. Multivariate analyses adjusted for all confounding factors, showed that patients managed by GP-Ho and GP-Mx used less psychotropic drugs over twelve months (OR=0.29; 95% CI: 0.19-0.44, and OR= 0.62; 95% CI: 0.41-0.94, respectively) compared to the GP-CM group, while remission rates were superior in the GP-Ho group (OR=1.70; 95% CI: 1.00-2.87) and comparable in the GP-Mx group (OR=1.49; 95% CI: 0.89-2.50). Suicide attempts and injuries were too few for adjusted analyses.

**Conclusion:** Patients seeking treatment for sleep, anxiety and depressive disorders from GP-Ho, GP-Mx and GP-Ho are comparable in terms of severity of their disease. ADD patients seen by homeopathic physicians and followed twelve months used less psychotropic drugs and showed a higher clinical remission rate of anxiety and depressive disorders in comparison with patients seen in conventional medicine practice, without loss of therapeutic opportunity .

**Economic evaluation of the Bristol Homeopathic Hospital: Final results of the BISCUIT feasibility study**

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**Aim:** NHS commissioners need to know if services reduce NHS costs such as GP consultations, hospital visits and medications to inform their funding decisions. The aim of the BISCUIT study was to test the feasibility of economic evaluation of homeopathic packages of care from the Bristol Homeopathic Hospital.

**Methods:** Using a prospective matched controlled cohort design, 15 case participants from the Bristol Homeopathic Hospital and 19 community controls were matched for GP practice, condition, age and sex. We collected data on personal and NHS costs, wellbeing and quality of life five times over 15 months. GP medical record data were extracted on NHS resource use for all 34 BISCUIT participants. Descriptive analyses from a NHS cost and societal cost perspective were carried out by an independent statistician. To identify key attributes of value for a Discrete Choice model, we interviewed Bristol Homeopathic Hospital patients. Interview data were analysed using a framework approach.

**Results:** Recruitment and 'good enough' matching of case and control participants were key issues. Cases and controls were well matched for quality of life and wellbeing, but not for resource usage at baseline. There was no difference in resource utilisation 12 months after baseline ( $p=0.70$ ). Individual variability in resource utilisation for both cases and controls was substantial. Quality of life for case participants improved compared to controls ( $p=0.056$ ). Wellbeing for case participants changed significantly compared with controls ( $p=0.007$ ). Qualitative analysis found that the attributes of greatest value in terms of homeopathic treatment were positive impact on health, questioning skills and personalised approach. The attributes of greatest value in service provision were extended consultation length, clinic location and free delivery.

**Conclusion :** Results should be taken with caution. However, findings suggest that homeopathic packages of care offered by the Bristol Homeopathic Hospital may have an impact on quality of life and wellbeing. But further work is needed to devise methodologies to robustly test resource usage, especially given the substantial variation in resource usage amongst individuals.

**Quantum coherence domains and nanoparticles – one and the same thing?**

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Understanding the physics behind the action of homeopathic dilutions has recently gathered momentum with the new links that have been drawn between homeopathy and the burgeoning field of nanoparticles. The advantages of such a connection are clear in that this relation brings homeopathy research into the fold of conventional material sciences. And it is all the more attractive in that nano-pharmacology is an emerging field of research which is currently drawing a lot of attention and consequently research funding. On the other hand we have theories such as the Quantum Coherence Domains (QCDs), which have previously been put forward to explain homeopathic dilutions, immediately begging the question as to whether these quantum domains have anything to do with conventional nanoparticles.

In this presentation I will offer an overview of Quantum Coherence Domains and how they differ and contrast from nano-particles. I will then put forward the idea that QCDs are to be considered as nano-particles themselves, albeit of a different type entirely from those that have been studied until now. I will present the way in which these quantum-nano-domains are formed and how they are able to record specific information. The way this information is then fed back to the patient will be presented, showing how it can modulate the complex sets of biochemical interactions at the basis of homeostasis.

I will present evidence that quantum-nano-domains offer greater explanative power than conventional nanoparticles in a number of experimental settings. The evidence for these quantum-nano-domains will be reviewed, highlighting areas which remain problematic, and those open to further investigation and replication.

In the end we are still faced with a very complex problem, we are only slowly unravelling. At the present time many indications point towards the idea that nanoparticles of some type are involved in homeopathic dilutions. These ideas need to be verified experimentally, confirming or infirming the different hypotheses, furthering and bringing needed clarity to this crucial field of research.

## Economic evaluations of homeopathy: A review

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**Context:** Economic evaluations of homeopathy are needed as part of the overall evidence-base of homeopathy. Such evaluations are of importance for patients, practitioners, policy makers and other stakeholders. Only limited evidence has been provided in previous reviews. There is a need to assess current research evidence of economic evaluations of homeopathy and to discuss recommendations for future research.

**Objectives:** To review and assess existing economic evaluations of homeopathy.

**Methods:** A review based on articles retrieved through databases and other sources. Databases used: AMED, Cochrane LIBRARY, CRD (DARE, NHS EED, HTA), EMBASE, MEDLINE. Other sources: *Homeopathy* (the journal), reference lists and contact with other authors.

**Results:** Sixteen economic evaluations of homeopathy fulfilling the inclusion criteria were identified. Studies included a total of 3.700 patients who received homeopathic treatment. Ten studies reported on control group participants. Ten out of 16 studies identified cost savings and health improvements. Four studies found improvements comparable to control group participants, at similar costs; and two studies at higher costs. Studies were highly heterogeneous and had several methodological weaknesses.

**Conclusions:** The overall evidence suggested cost savings and potential benefits of homeopathy. Studies did however have several methodological weaknesses and were highly heterogeneous, limiting the possibility to draw firm conclusions. We present recommendations for future research.

**Homeopathic medication in pulmonary tuberculosis treatment, clinical evolution, and drug-resistance: a randomized, double blind clinical trial**Jorge Biolchini\*; [Dr Sofia Wenna](#), MD\*

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Tuberculosis (TB) is a serious worldwide public health problem, with high rates of incidence, prevalence, and mortality. Nearly one third of the world population is infected with *Mycobacterium tuberculosis*. TB prevention and treatment represent a considerable financial burden for society. Up to 2015 US\$ 8 billion per year will be needed in the most affected countries. Until the present day there is no effective vaccine to prevent TB in adults. Multi-drug resistance in TB treatment (MDR-TB) is increasing worldwide. Globally, 3.7% of new cases were estimated to have MDR-TB, as well as 20% of previously treated cases. Besides, the average proportion of MDR-TB cases with extremely drug-resistant tuberculosis (XDR-TB) is 9.0%. A significant effort is being addressed to develop both new drugs to treat drug-sensitive or drug-resistant TB, and eleven vaccines to prevent TB. Globally, the treatment success rate among all newly-diagnosed cases has been 85%, and 87% among patients with smear-positive pulmonary TB (the most infectious cases). This figure reveals a rate of about 15% unsuccessful treated cases, which poses an impact on population treatment time, cost, efficacy, and safety. Regimen for most patients with MDR-TB takes 20 months. Cost of drugs alone for treating the average MDR-TB patient is 50 to 200 times higher than for treating a drug-susceptible TB patient. Besides, second-line anti-TB drugs can have serious side-effects, while being less potent. In a broader perspective of the disease progress, these consequences are major causes for treatment abandonment, a factor that contributes to increasing the number of new infected patients. The objective of this study is to evaluate the influence of the homeopathic medicine *Tuberculinum bovinum* in patients treated for pulmonary tuberculosis, with first-line anti-TB drugs RHZE (isoniazid, rifampicin, pyrazinamide, and ethambutol). A prospective, randomized, placebo-controlled, double blind trial is being conducted with 50 adult patients at the tuberculosis control unit of the Hospital Federal dos Servidores do Estado (Federal Hospital of State Workers), in the city of Rio de Janeiro. All patients met the following criteria for entry into the trial: male or female, sputum smear-positive pulmonary tuberculosis, beginning of anti-TB treatment. Patients diagnosed either with extra-pulmonary tuberculosis, or non-first-line RHZE treatment, have been excluded. The rationale for this last criterion was due to the fact that RHZE is the most commonly used anti-TB drug scheme, has the shortest duration, and yet could potentially have its success rate improved. Data is collected in a regular basis, along 6 months of treatment, by using questionnaires for first consultation and follow-up. Information analyzed includes clinical and laboratorial features of the tuberculosis disease, and individualized characteristic patterns of patient and his/her evolution. Outcomes of the study include difference between the homeopathic medication and placebo in: clinical evolution of the disease, clinical evolution of patient miasmatic pattern, antibiotic resistance development, RHZE adverse effects, and tuberculosis resulting sequelae.



# Poster Presentations

**P1:** Dr Sergio Abanades

Fri 31 May, 17.00

## **Development and implementation of a research-training program in homeopathy within the Master's degree for medical doctors of the University of Barcelona (UB)**

Sergio Abanades, Marta Duran, Maite Bravo and Gonzalo Fernandez  
AMHB, Barcelona, Spain.

**Introduction:** There is a growing offer of homeopathic courses in Europe. Nevertheless, there training in evidence-based research in homeopathy is not always available. The scientific evidences of homeopathy are crucial for the integration of homeopathy in public health. Thus, knowledge in this field is necessary for novel and experimented homeopaths to understand evidence-based medicine (EBM) and contribute to generate valid scientific data.

**Aims:** The aim of this project was to design and implement a clinical research training in homeopathy within the Master's degree for medical doctors (MDs) of the University of Barcelona (UB), Spain.

**Methods:** The Master's degree for medical doctors of the University of Barcelona (UB) is a two-years course based on the "Basic Teaching Standards in Homeopathic Medicine" approved by the European Committee of Homeopathy. A research programme was designed by two MDs clinical researchers, specialised in both clinical pharmacology and homeopathy. The program is divided in four major areas: 1) review of the scientific evidences of Homeopathy following EBM standards (basic science, effects of ultradilutions, effects in healthy volunteers, clinical evidences) 2) developing critical reading skills in EBM and pertinent analysis of relevant homeopathic research publications 3) training in developing an EBM research protocol and in planning, developing and publishing a scientific paper. 4) Preparation and presentation of the pertinent research dissertations work.

**Results:** Since 2010 60 MDs and veterinary doctors have been trained in this program enhancing their knowledge of evidence-based homeopathy and their research-related skills. Dissertation's work comprise several different research areas including veterinary research, design and execution of "provings", design of randomised and controlled clinical trials, epidemiological studies, studies in healthy humans, replication of previous published work etc.

**Conclusions:** Training in homeopathic research increases the awareness of the scientific evidences of homeopathy and can contribute to increase the generation of valid scientific data in homeopathy. This can enhance the quality of clinical reports and observational studies and promote adequate clinical trials to answer clinical practice research questions.

**Quality assessment and response to the Spanish Health Minister's report regarding the scientific clinical evidences of homeopathy**

Sergio Abanades, Marta Duran

Research department of AMHB, Barcelona, Spain

**Introduction:** On December 2011 the Spanish Health Minister's presented a report concerning the situation of natural therapies in Spain. This report included an analysis regarding the clinical scientific evidences of Homeopathy.

**Aims:** To analyse the scientific basis of the report and to perform a scientific update based on a systematic review regarding the clinical scientific evidences of Homeopathy.

**Methods:** A quality assessment of the report and a systematic review of systematic reviews was performed in Medline, Embase and Cochrane Database of Systematic Reviews, search date up to December 2011. Search term used was "homeopathy" and hand search was also performed for the main digital homeopathy libraries.

**Results:** The Spanish Health Minister's report is limited by several methodological flaws which prevent the generalization of its results 1) Inclusion/exclusion criteria are not specified for the 9 studies included, therefore selection bias can not be excluded. 2) The flux of studies found and analysed are also not specified 3) Scores and scales used to evaluate the quality of the studies are not indicated 4) Studies were limited to some reviews in single medical conditions; 5) The bibliographic research was limited up to 2007, nonetheless conclusions were generalised to 2011. In the review performed by our team, 30 systematic reviews/ and Meta-analysis were found in addition to the 9 reviews described in the report. These reviews analyse the efficacy of homeopathy in 23 clinical indications, 14 more than the ones included in the report. There are convincing high quality scientific clinical evidences in several indications as diarrhoea in the childhood, high respiratory track infections or radiodermatitis.

**Conclusions:** The Spanish Health Minister's report is not a systematic review of the literature and is limited by several methodological flaws, which prevent the generalization of the results. There are strong scientific evidences in some clinical indications, which demonstrate measurable significant clinical effects of homeopathy beyond a possible placebo effect.

## Homoeopathy in Tuberculosis

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### Background:

Globally India accounts for one fifth of new Tuberculosis (TB) cases. TB kills more adults in India than any other infectious disease. India has gone through two phases of TB control after availability of effective chemotherapy for TB namely : (1) National Tuberculosis Program (NTP) and (2) Revised National Tuberculosis Control Program (RNTCP)

TB treatment has seen different eras from only supportive treatment through sanatoria, monotherapy, combination therapy, domiciliary treatment, long term (conventional treatment), short course treatment, intermittent and now finally to a now-a-days popular Directly Observed Treatment – Short Course (DOTS).

### Methods:

Tuberculosis (TB) has been known since antiquity. In spite of effective antibiotic treatment,

it is still a major worldwide public health problem. Endogenous factors are important in the development of active disease. Homeopathic medicines have the potential for immune-modulation and hence to influence endogenous factors in disease.

In India, patients with tubercular lymphadenitis (TBLN) often consult homoeopaths but such cases are seldom documented. The objective of the present study is to document such experience.

A retrospective exploratory study of 25 positively diagnosed cases of TBLN has led to the development of a homoeopathic regime consisting of:

- a patient specific constitutional medicine,
- one disease specific biotherapy (Tuberculinum) and
- Silicea 6x as supportive medicine.

Homeopathy can be used as a complement to conventional anti tubercular treatment (ATT) with beneficial results. Further validation in controlled trials with immunological markers is required.

**Keywords:** Tubercular lymphadenitis; Endogenous factors; Retrospective exploratory study; Homoeopathy; Constitutional treatment; Tuberculinum; Silicea

**Conclusion:** Homeopathy can be integrated as an add-on/ complementary medicine to conventional anti-tubercular treatment of Tuberculosis for better compliance and outcome ratio. Hence, a combined approach (Allopathic and Homeopathic ) could be an answer in the prevention and treatment of Tuberculosis.

## **Research into the effectiveness of homeoprophylaxis for infectious disease prevention**

Kate Birch RSHom(NA), CCH and Cilla Whatcott HD (RHom) CCH (co-presenters)

Due to the alarming incidence in vaccine related injuries and NPDD in North American children we have embarked on the task of testing another way to prevent disease. Due to the work of Dr. Isaac Golden in Australia with homeoprophylaxis (HP), and Gustavo Bracho of the Finlay Institute in Cuba, for their work on Leptospirosis, under the umbrella of research into HP, we are providing access to a 44-month self-administered HP program in North America (US and Canada).

Since 2009, 300 children are partaking in the program at various levels of completion. By June 2013 we expect there to be about 400. These children are being tracked for the duration of the program and results in effectiveness of disease prevention collated. In 10 years our projected enrollment is expected to be up to 2000 children. At that time we expect to have a substantial body of evidence demonstrating the effectiveness of HP and the long-term health outcomes of participating children. Our goal is to increase access to HP globally through our ongoing education and support programs.

### **Parameters surveyed**

- Some of the participants will undergo blood testing to determine antibody levels to the respective diseases.
- Independent agencies have previously collected, or will collect, the data on the health status of vaccinated children.
- Results of effectiveness of HP towards disease incidence will then be compared to that of children who have undergone current state vaccine schedules.
- Surveys into the overall health of participants will also be collected.
- These results will then be compared to the overall health of vaccinated children.

### **Significance of this study**

- Currently the US has the highest vaccination rate of any country
- The US has the highest Autism rate of any country, not to mention, allergies, asthma, skin conditions and other NPDD
- There are legal pressures to take away vaccine exemptions
- There is no other approved method of infectious disease prevention available in the US besides vaccines
- Access to nosodes in the US is at risk

Effectiveness of HP will be determined by patient compliance, disease incidence vs exposure, and general health outcomes. Efficacy will be determined by blood titers draws and antibody levels and disease incidence vs exposure. Rather than testing

each disease nosode individually here we are using the complete HP program (8 diseases) as a substitution for vaccine program. This offers some assurance to parents who, while they are not interested in vaccinating their children, are looking for some way to protect them from infectious disease. To test each nosode individually would take too much time and would also put the children at risk for other infectious disease.

In May 2013 we will present our to-date findings, including the number of children enrolled in the program, number exposed to disease, number who contracted the disease and the on-going health outcomes. In addition to the statistical analysis generated we will overview the philosophy behind HP, how systematic use of nosodes actually stimulates a higher level of health, and how the program can be replicated in a variety of countries and settings around the world.

## **A critical examination of evidence regarding the use of individualised homeopathy in the treatment of bipolar spectrum disorders**

Kimberlee Blyden-Taylor, ND

### Introduction:

Diagnosis of bipolar spectrum disorders has substantially expanded in scope due to changing diagnostic criteria. As a result, the societal and economic impact of these disorders has garnered greater public awareness and concern. My interest in this topic stems from the increasing number of patients presenting in my clinical practice over the past decade with bipolar spectrum disorders and the co-morbid conditions (substance abuse, OCD, eating disorders, unemployment, and family trauma) that too often appear in its wake. The aim of this paper is to identify evidence in regards to individualised homeopathic treatment of patients with symptoms of bipolar spectrum disorders.

### Method:

A literature review was undertaken to determine published evidence of the effect of individualised homeopathic treatment for bipolar spectrum disorders.

### Results:

Ten relevant articles were identified. Claims for the effect of homeopathy for bipolar disorders exclusively include documentation of single cases. Cases are presented as informal abbreviated interviews or as summaries, and generally include some degree of analysis in regards to remedy choice. Strengths of single case reports include detailed descriptions of patients' symptom pictures and length of follow-up periods. Weaknesses include the varied quality of published case reports, lack of diagnostic criteria, lack of triangulation for content validation, and a lack of standardization making cross case comparison unreliable. Case reports are typically retrospective and generally do not include rival explanations for positive changes. To date, no clinical trials have been published.

Conclusion: Documentation of the successful effect of individualised homeopathy in treatment of bipolar spectrum cannot reliably be said to exist at this time. Informal single case reports are a historical backbone of knowledge transfer in the homeopathic community and have provided great depth of insight into practitioners' methodology as well as patient experience. However, lack of consistency in the style and quality of case reporting and in the rigour of analysis limits cross-case comparison and generalizability.

Thompson's (2004) innovative Formal Case Study (FCS) approach offers a viable alternative to the standard case report as it was specifically created to address the inherent weaknesses of that format. FCS is grounded in established practices of qualitative research; it utilizes grounded propositions which are tested by a variety of analytic tools, focusing on identification of deviant cases and rival explanations of outcomes. Although it requires more work on the part of the homeopath-author, the

FCS offers the potential for building a clinically useful database of cases amenable to cross-case comparison and generalizability. Whole Systems Research (WSR) offers further research potential into the synergistic effects inherent in complex treatment systems. Although this work is still in the emergent phase, potential exists for rigorous assessment of the synergistic effects of multiple components of the homeopathic process, such as the patient-practitioner interaction, the interview process, and the remedies. A key strength of WSR is model validity which requires the research to adequately reflect the unique healing theory and therapeutic context of the intervention being assessed. Whole systems research suggests combining modified RCTs such as pragmatic trials, factorial designs and n-of-1 trials with qualitative methods to adequately explore the meaning, process and context by which healing occurs.

References: Thompson, T.D.B. (2004) Can the caged bird sing? Reflections on the application of qualitative research methods to case study design in homeopathic medicine. *BMC Medical Research Methodology* Vol. 4, No. 4.

## Treatment of chemotherapy related fatigue: an opportunity to use the n-of-1 trial design in individualized homeopathy

David Brulé<sup>1</sup>, Dugald Seely<sup>2</sup>  
Riverdale Homeopathic Clinic, Toronto, Canada

**Background:** Cancer-related fatigue has been described as a subjective feeling of physical, emotional, and/or cognitive tiredness. Fatigue has a multidimensional component with correlations to other symptoms such as pain, insomnia, anorexia, nausea, vomiting, anxiety and depression. Homeopathic treatments show some potential in relieving cancer-related fatigue, are easy to deliver and demonstrate strong compliance.

The n-of-1 trial design is a scientifically rigorous method of studying particular clinical conditions. The method involves the administration of either verum or placebo according to a binary randomization allocation sequence unknown to both the clinician and participant. During the subsequent treatment period the participant will be given the other allocation (verum or placebo). The following pairs of allocations will also be randomized with treatment continuing for as long as the participant is in the trial.

Using the n-of-1 design to test the efficacy of homeopathy is challenging primarily due to the unpredictability of the length of time of the effects of homeopathic treatment. On the plus side, the individualization of homeopathic treatment can be harnessed by repeated testing in a single participant. This may be especially fruitful in an individual who is sensitive to or who seems to respond actively to homeopathic substances.

**Methods/Design:** An n-of-1 pilot trial of individualized homeopathic treatment of fatigue in a single adult who is undergoing any type of chemotherapy administered intermittently (i.e. not continuously) will be performed. The participant will have a homeopathic consultation within 3 days of a round of chemotherapy (“treatment period”) and will be administered either verum or placebo according to the n-of-1 design. The pairs of allocations will continue for as long as the participant is undergoing chemotherapy treatment. Each round of chemotherapy will provide a consistent washout thus reversing any of the prior effects of the homeopathic remedy. The washout and reversibility in this particular clinical context (in which a highly toxic chemotherapy and antidote is given) will provide one of the key requirements for effective application of the n-of-1 design.

The primary objective of the study is to establish the feasibility of the n-of-1 design in studying individualized homeopathic treatment in a cancer patient experiencing fatigue as a result of their chemotherapy treatment. We will track the following:

1. the ability of the participant to stay with the study and to fill out all of the questionnaires. the time it takes to recruit a single eligible patient and number of screens to find this patient,
2. clinical effect size via changes in scores according to the Multi-dimensional Fatigue Inventory (MFI) and the EORTC-QLQ-C30 based on use or not of the homeopathic agent to establish potential benefit or lack thereof in one individual.

**Discussion:** This pilot study is a critical step in order to determine whether future n-of-1 trials of individualized homeopathy are feasible in individuals undergoing chemotherapy. Ultimately, homeopathy may be an effective treatment for fatigue with minimal potential to interact with chemotherapy and affect anti-cancer activity and potential for cure.

## A Research Tool for Homeopathic Practice

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Clinical outcomes studies are designed to evaluate the effects and/or efficacy of a treatment or modality. Clinical research is mostly carried out by trained academics and is perceived to be beyond the scope or capability of the general homeopathic practitioner.

I believe that rigor in homeopathic practice is just as important as in clinical trials. Homeopathic educators present and publish mostly their best cases. The realities of practice are often very different from the perceived brilliance of their teachers. COMPASS is a software program with a tremendous number of in-built audit tools designed by homeopaths to help homeopathic practitioners examine and evaluate many aspects of their work – not just the effects of individual prescriptions. Computers are brilliantly placed to help homeopaths keep track of the myriad details of each case and to calculate certain aspects of carefully entered data. COMPASS helps homeopaths in practice evaluate the results of their work. It provides a way for homeopathic practitioners to conduct a variety of outcomes research without getting a degree in statistics or research proper.

### Session Goals

- To inspire educators to include outcomes research instruction into their teaching programs – especially their clinical training.
- To discuss how practitioners in general practice can evaluate the results of their work on a regular basis to describe some of the many benefits of this practice.
- To illustrate the numerous audit features and explain their purposes and values.
- To generate discussion around this area of grass roots homeopathic clinical research.
- To solicit feedback regarding possible improvements.
- To seek collaboration with others doing similar research.

**Epidemiology of anxiety disorders in primary care and drug prescription by conventional practitioners favourable to homeopathy**

DIAZ-SAEZ G, ECHEVARRIA E, TERZAN L, TORRE-ENCISO L

Speciality in Family Medicine and Homeopathy; Coordinator of Research at the Chair of Homeopathy of the University of Zaragoza, Medical Director at Boiron

**Introduction:** Anxiety disorders (AD) have become the most prevalent psychiatric disorders in the general population and the number of cases coming to the primary care physician is increasing in recent years. This study aims to determine the clinical-epidemiological profile of these patients and to know the true of their management in the Primary Care setting as well as the impact of the different treatments on their short-term evolution.

**Materials and Methods:** Epidemiological survey completed by 15 investigators in the Primary Care setting who had declared to be familiarized with homeopathic drugs, with a total of 110 recruited patients followed in three scheduled visits during 60 days of follow-up. The following data were collected from patients: clinical-epidemiological data, history of AD, information on pharmacological and adjuvant treatments, assessment of the level of anxiety (Hamilton-HAM anxiety scale), the anxiety status perceived by the patient (Visual Analogue Scale - VAS) and evolution of the general state of well-being (using the Clinical Global Impression Scale - CGIC).

**Results:** The mean age of the population studied was 42.5 years (n = 108) and 70% were female. Thirty seven percent (37%) of patients presented a first-degree family history of AD. The most frequent AD were generalized anxiety disorder (32.7%) and panic disorder (30%). Comorbidity in AD fluctuates from the initial 19% to 38.9% in the bimonthly assessment, being the most usual association the generalized anxiety disorder with the panic disorder. The use of combination treatments was predominant over monotherapy and the most frequent combination (27.3%) was selective serotonin reuptake inhibitors (SSRI) in combination with benzodiazepine (BDZ) and Sedatif-PC, the most common homeopathic treatment. Homeopathy was used by 74.5% of patients and 50% of those used other adjuvant treatments. Patients who had more symptoms of anxiety based on Hamilton Anxiety Scale were those most heavily treated and the administration of treatment caused an improvement in CGIC in all groups studied. The perception of improvement by the patient according to VAS scale was significant only in patients treated with homeopathy (Sedatif-PC).

**Conclusions:** AD affects women more frequently than men and prevalence rates are high in midlife and in subjects with a first degree family history of AD. The extensive use of pharmacological treatment, mainly with BDZ and SSRI is the standard of care for AD. The use of adjuvant therapies such as Sedatif-PC, in combination with other drugs or alone, is nowadays perceived by physicians as an interesting therapeutic tool for the improvement of the anxiety symptoms, with the advantage of having no side effects and promoting a more favourable general health status in these patients.

## **PH-DA: a protocol for observational real-life study of homeopathic treatment of atopic dermatitis in the outpatient private and institutional setting**

José E. Eizayaga & Silvia Waisse

Faculty of Homeopathy Health Sciences Maimonides University

**Background and aims:** Atopic dermatitis (AD) is a chronic non-infectious skin inflammatory disease, mostly affecting children, whose incidence and prevalence are increasing in developed and developing countries, affecting the quality of life (QOL) of both patients and caregivers. Conventional medical treatment is mostly restricted to long-term use of emollients and corticoids, with the consequent adverse effects. In homeopathy, AD represents about one-third of outpatient visits due to skin-related complaints, however, the efficacy and effectiveness of homeopathic treatment are controversial, whereas most studies do not take into account the real-life conditions of homeopathic clinical practice. The aim of the present study was to develop an observational real-life research protocol applicable to the actual conditions of outpatient homeopathic practice in the private and institutional setting.

**Methods:** Based on our previous experimental results, we elaborated and tested in a multicenter pilot project one earlier version of the protocol (PH-DA) including objective scores of AD severity, generic and DA-specific quality of life questionnaires, and several outcomes measures, which proved to be too complex and time-consuming to be widely and feasibly applied by homeopathic practitioners. On these grounds, further research, and discussions with international experts including CR Charman, we made modifications in the original PH-DA allowing for faster and more accurate measures. Therefore, the outcomes of PH-DA include: 1) one measure of AD severity, TISS (Three Item Severity Score), whose completion demands less than one minute; 2) self-reported global measurement of AD severity; 3) self-reported global measurement of AD-related QOL; 4) self-reported POEM (Patient Oriented Eczema Measure), a validated score with satisfactory correlation with QOL questionnaires; and 5) self-reported assessment of DA progression and wellbeing by means of ORIDL (Outcome Related to Impact on Daily Living). The latter four might be self-administered at the waiting room. The remainder of data (sociodemographic, clinical history, and homeopathic diagnosis and treatment) are the homeopathic medical standard ones and do not demand extra effort from practitioners.

**Expected results:** PH-DA might represent a practical, reliable, and accurate tool to establish the effectiveness of homeopathic treatment in real-life institutional or private outpatient clinical practice, and eventually might also be applied to RCTs to test efficacy. This latest version of PH-DA is currently subjected to multicenter pilot testing at the Department of Homeopathy of the Faculty of Medicine of Maimonides University, Buenos Aires, Argentina, and the Outpatient Clinic of the São Paulo Medical Homeopathic Association, Brazil, affiliated with the Brazilian national health system. The results will be communicated at HRI International Homeopathy Research Conference.

**Potassium dichromate (homeopathic Kali bichromicum) in the community hospital. Intensive Care Unit setting: a review of sixteen cases****Joyce Frye DO, MBA, MSCE**

Center for Integrative Medicine – University of Maryland

**Purpose:** An RCT at the Univ. of Vienna, reported mean 3.5 day reductions in time to extubation and discharge from an ICU in a group treated with homeopathically potentized potassium dichromate (Kali bichromicum 30C, KB). Subjects were mostly men in their late 60s with a >10-yr smoking history on mechanical ventilation (MV) due to exacerbations of their Chronic Obstructive Pulmonary Disease. Exclusion criteria included lung disease in addition to COPD; positive blood culture; airway obstruction; heart disease; and need for catecholamines. (Frass, Dielacher et al. 2005) Subsequently, KB was approved for use at two rural community hospital affiliates of a major U.S. medical center. A review of the cases treated was undertaken to gain a better understanding of the use of KB in the community hospital setting.

**Methods:** The local institutional review board approved onsite review of charts in the electronic medical record (EMR). Sixteen patients for whom KB had been ordered from September 2009 to March 2011 were identified by the inpatient pharmacy director in a search of the dispensing database. EMRs were reviewed to note diagnoses, days on MV prior and after introduction of KB, ventilator settings, and sputum description. The pulmonary physician who had obtained approval for use of the drug also supplied brief comments for some patients, which had been prepared for the Pharmacy & Therapeutics Committee.

**Results:** The inpatient pharmacy obtained KB in blue plastic tubes containing 38 mm medicated lactose pellets (BoironUSA, Newtown Square, PA) from a local community pharmacy. ICU nurses administered five pellets sub-lingually bid. The requisition for KB most often came from the pulmonary consultant; although he was not the primary physician in any case. Timing of KB was inconsistent; in several cases it seemed a last-ditch effort after many days of intubation, and the patient succumbed. No patient would have met inclusion criteria for the Vienna study and all had multiple co-morbidities; yet consistent sputum descriptions suggest that the concept of “genus epidemicus” may be applied to some medical conditions beyond the epidemic situation. Physician observations were generally favorable.

**Conclusions:** Methodology for assessing generalizable “real-world” use of homeopathic medicines is critically needed. Utilizing propensity scores and linear regression modeling may provide one such method for future pragmatic clinical trials.

## Can quality in professional education and training be characterised by three opposing pairs of core categories? Findings from a qualitative, single case study of the education quality at a small private complementary medicine college in Switzerland

Ulrike Kessler, MSc<sup>1</sup>, Kate Chatfield, MSc, MA, MNWCH

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### Background

Public desire for complementary medicine in Switzerland is highly evident with over two thirds of the population voting in a national referendum in May 2009 in favour of complementary medicine being included in the Swiss constitution. Education for complementary medicine practitioners in Switzerland is undertaken in the private sector with wide variation in pedagogical approaches and quality assurance procedures. However, the public interest in complementary medicine necessitates an assurance of public safety and professionalism of service.

### Objectives

The study sought to investigate how the college defines its aims and objectives for homeopathy training and to what extent those objectives are realised in practice.

### Methods

This study was conducted between September 2009 and August 2010. It utilised a qualitative, single case study approach to examine a college offering part time professional education and training for practitioners in complementary medicine in Switzerland. Grounded Theory was used as a methodological framework for collecting and analysing the data.

### Results

The results of this study appear to empirically confirm previous findings which, for quality Professional Education and Training, have emphasized the importance of aligning a teaching programme with the aims and objectives of an education: *Coherence*, effective and transparent communication: *Transparency*, and taking into account the *Student-interest*.

### Conclusions

Consideration of the emergent themes of this study has resulted in formulation of a tentative hypothesis, that three opposing pairs of core categories (or dimensions of quality):

- *Separateness – Coherence*,
- *Opaqueness – Transparency*, and
- *Self-Interest* (of the course provider or institution) – *Student-interest*, are able to characterise quality in Professional Education and Training.

**A review of use of enantiomers in homeopathy**

Dr Michael Kuzeff. Email: [kuzeffm@yahoo.com.au](mailto:kuzeffm@yahoo.com.au)

Many molecules in nature have geometry, which enables them to exist as non-superimposable mirror images, or enantiomers. Modulation of toxicity of such molecules provides possibility for therapeutics, since they target multiple points in biochemical pathways. It was hypothesized that toxicity of a chemical agent, could be counteracted by a homeopathic preparation of the enantiomer of the chemical agent (Patents applied for: PCT/AU2003/000219-PCT/\*\*AU2008/001611).

A diverse body of data, including controlled laboratory studies using several species and compounds, supports the conclusion that toxicity of optical isomers may be inhibited by homeopathic enantiomer preparations. These data were obtained with minimal or no pre-testing to determine optimal test solutions suggestive of a robust hypothesis. Inhibition of the excitotoxic neurotransmitter L-Glutamic acid with homeopathic preparations of D-Glutamic acid, indicates the latter may be of use for amelioration of symptoms of disturbances of mood. This is an example of hypothesis driven research using homeopathy. Potency chords seem more stable in action than simplexes.

The abstract presentation will touch on recent work summarized in the review article at <http://www.hindawi.com/isrn/toxicology/2012/575292/>, and also point to some of the numerous scenarios where it may be possible and relevant to investigate action of enantiomers in homeopathy.

### Assessment of a new decision support expert system in headaches cases

Lilas Theodoros, Tapakis Eleftherios.  
Greece

Continuous advancements in Information and Communication Technologies along with the consequent massive adoption of *Web services provide today, exciting and effective decision support tools for many professions. The vital need for high levels of accuracy and effectiveness in homeopathic prescribing was the driving force behind the development of a new online expert system.*

VithoulkasCompass is a web-based decision support tool, designed to aid the homeopathic practitioner in finding the individual correct remedy, by inputting relevant symptoms. Calibration and refinement of the algorithms and mechanisms that lead to the proposal of the correct remedy by the expert system are the key areas of continuous, on-going research, always confirming new developments against a very large number of real world cases from the archives of the International Academy of Classical Homeopathy (IACH).

A statistical assessment of VithoulkasCompass expert system platform has been performed on chronic headache cases. The methodology included two phases.

1. It analysed the performance of the software on cases already solved by homeopathy experts (and specifically Professor's George Vithoulkas), comparing the remedy provided by the human expert with the corresponding proposal of the system.
2. It assessed the support that the software provides live – in front of the patient - on cases solved by less experienced homeopaths. This evaluation process is based on statistical analysis of success rates derived from the assessment of the follow up on patients' cases, according to the principles of classical homeopathy.

The first phase was initiated with the selection of successful cases from highly skilled expert homeopaths. Successful cases are cases where follow ups clearly indicate that the remedy acted curatively. After repertorisation of the cases an assessment process was performed on how accurately the proposed, software-generated remedies, successfully matched the human-prescribed remedies.

The second phase was about reviewing cases solved by homeopaths with the support of VithoulkasCompass expert system. After the initial input and the analysis of symptoms, a first set of proposed remedies was provided by the system. If the case was clear, the homeopath proceeded with the appropriate prescription. If the case was not clear, the differential analysis functions of the software were utilized in order

## Homeopathic research in palliative care (PC) - A review of modern studies concerning the field of PC

Dr Isidre Lara i Llobet

Federación Española de Médicos Homeópatas (FEMH), Spain

### *Introduction*

Homeopathy, with a tradition of use without discontinuity in nearly all over the world longer than 200 years, stands as one of the complementary and alternative medicines (CAM) that could offer effective alternatives of treatment in palliative care, not yet fully explored or investigated. Observational studies support its use in the field of PC to reduce anxiety, depression, and to improve quality of life, also to reduce hot flashes and breathlessness.

### *Objectives and method*

Review of indications and possibilities that homeopathic treatment offers in the field of PC from modern investigations, confirming somehow classical homeopathic authors tips. Review of bibliography of *Encyclopaedia Homeopathica*, review of summaries of searches in PubMed, Medline and Cochrane Database of Systematic Reviews.

### *Results*

Homeopathic treatment offers effective alternatives of symptoms control in several clinical situations that appear in persons at the end of life.

The review has been done for those clinical situations that have been studied with modern research methodology, after selection of the best studies and with more significant results, adding tips from classical homeopathic authors. Clinical situations selected are: -emergencies; -cancer; -prevention and treatment of iatrogenical oncological conventional treatment (radiotherapy, chemotherapy, surgery); -(oncological) pain; -infections; -digestive symptoms; -respiratory symptoms; -skin symptoms; -agony.

### *Conclusions*

Homeopathy is an alternative/complementary therapeutics effective to relieve physical, emotional, psychological and spiritual suffering of the sick at the end of life; could reduce the necessary charge of conventional chemical medication, reducing its secondary effects and improving their tolerance, being of easy administration, without pharmacological interactions and with minimal secondary effects; contributes to the understanding of how patient lives the end of life and his needs; could improve quality of life and dignity of the patient at the end of life, diminishing the suffering; could improve probability of survival, and, when time is coming, quality of death (euthanasia).

**Keywords** Homeopathy in palliative care; Palliative care; Terminal illness.

to suggest symptoms not revealed by the patient and to finally single out the correct remedy. Along these lines, the contribution of the differential analysis function was also effectively assessed.

A team of scientists guided by Prof. Vithoukias of the IACH and the Aegean University evaluated the results of the system and the curative effect of the consequent administered remedies.

Statistical analysis demonstrates that VithoukiasCompass expert system, has a very high accuracy in proposing appropriate remedies for treating patients suffering from chronic headaches, as well as showing high efficiency on individually prescribed homeopathic remedies, in many headache cases.

## **Usefulness of homoeopathy in essential hypertension: an exploratory interventional trial**

Dr. Pritha Mehra, MD (Hom.) Research Officer at Central Council for Research in Homoeopathy, New Delhi, India. Email: drpritha@gmail.com

**Background:** Hypertension has shown a significant increase in its prevalence not only in urban but also in rural population in India. Out of all hypertensive cases 85%-95% account for 'Essential hypertension', which is mostly attributed to genetic, psychological and environmental factors. Thus, there is need for a holistic approach for its treatment. Homoeopathy with its holistic concept, individualization, wide range of medicine and judicious application of auxiliary methods can prove to be a better option. This observational study as a part of thesis during post graduation was taken up to examine the usefulness of homoeopathic medicines in management of essential hypertension

**Objectives:** The primary objective was to evaluate the role of homoeopathic drugs in the management of essential hypertension. Secondary objective was to find out the cases which belong to 'Metabolic syndrome' as per the clinical criteria of National Cholesterol Education Program (Adult Treatment Panel (ATP) III).

**Methodology:** An exploratory interventional trial was conducted at Dharam Kiran Govt. Homoeopathic Hospital, Hyderabad from 2004-06. 30 cases were enrolled from the OPD of the hospital. Patients who fulfilled the inclusion criteria were enrolled in the study after receiving written informed consent. Medical history, physical examination, laboratory investigations were used to rule out Secondary hypertension. Detailed case history was recorded as per the standard case recording format and cases were repertorized using suitable repertory. Final selection of the medicine for each case was done in consultation with homoeopathic Materia medica. Modifiable risk factors like obesity, excess salt intake, alcohol consumption were recorded at baseline.

The cases with Stage II hypertension were followed up every 15 days and cases with Stage I hypertension were followed every one month till one year. Improvement status was assessed considering changes in staging according to Joint National Committee on prevention, detection, evaluation and treatment of high blood pressure VII report (JNC VII) and improvement in general condition. Main outcome measure was to assess the change in blood pressure in Stage I and II hypertension cases and secondary outcome was to find cases that belong to 'Metabolic syndrome'. Data was analyzed by using statistical software SPSS version 16.

**Results:** There were 16 (53.33%) cases showed marked improvement, 8 (26.67%) cases improved moderately, 3 (10%) showed no improvement and 3 (10%) cases dropped out. Arsenic album, Natrum muraticum, Nux vomica, Causticum and Lycopodium were found useful in the management of essential hypertension.

Wilcoxon's sign rank test was used to analyze the data. The values for both systolic and diastolic blood pressures before and after treatment were found statistically significant ( $p < 0.001$ ). Clinical presentation of essential hypertension as Metabolic syndrome was present in 46.67% of the cases.

Conclusion: This study found that the constitutional treatment based on homoeopathic principles offers the best therapeutic solution in the management of essential hypertension. Further well designed studies should be taken up to establish the efficacy of homoeopathy in management of non-communicable diseases like hypertension. This study found that the constitutional treatment based on homoeopathic principles offers the best therapeutic solution in the management of essential hypertension. Further well designed studies should be taken up to establish the efficacy of homoeopathy in management of non-communicable diseases like hypertension.

**“It’s the consultation, stupid!”...isn’t it?’ Complementarity and the shortcomings of Rcts**

Lionel R Milgrom<sup>a</sup> & Kate Chatfield<sup>b</sup>

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**Background:** For over 200 years, homeopathy has benefited many millions worldwide. Yet controversy still surrounds its *modus operandi* (e.g., the action of its potentised remedies), primarily because homeopathy is thought to violate basic reductionist principles of science and biomedicine. Against this, the relevance of RCTs has been questioned,<sup>1</sup> and alternative explanations of the efficacy of homeopathy/CAMs proposed, based on more holistic principles derived from quantum theory,<sup>1, 2</sup> e.g., non-locality and complementarity. Brien *et al* recently conducted a five-armed RCT of adjunctive homeopathic treatment in patients with active yet relatively stable rheumatoid arthritis.<sup>3</sup> While sizeable clinically relevant benefits were found, Brien *et al* attributed these *solely to the innately empathic nature of the homeopathic consultation*; not to any prescribed single or complex homeopathic remedy. The question posed here is whether quantum theoretically-derived notions of non-locality and complementarity, could shed a different light on the outcomes and meaning of Brien *et al*'s research.<sup>4</sup>

**Method:** Complementarity refers to seemingly contradictory phenomena when, *depending on experimental circumstances*, light and sub-atomic particles behave as wavelike or particle-like; it being impossible to observe both with absolute certainty *simultaneously*. Taken together, however, they present a fuller description of reality than either taken alone. Thus, what we observe (particle or wave) ultimately and intimately depends on the kind of experiment we do, i.e., the answer obtained depends crucially on how the (experimental) question is asked.

**Preliminary findings:** In suggesting specific and non-specific effects of a treatment are non-additive (i.e., the whole is greater than the sum of its parts), Weatherley-Jones *et al*<sup>5</sup> suggest a similar complementary relationship in RCTs of the therapeutic process. This was made explicit<sup>4</sup> when attempting to comprehend the results of recent RCTs of homeopathic provings in terms of non-local correlations between verum and placebo groups.<sup>6, 7</sup>

**Discussion:** Brien *et al* suggest the exact opposite: specific and non-specific effects of the therapeutic process are deemed additive (i.e., the whole IS the sum of the parts), and both are amenable to simultaneous testing via the RCT. An alternative

interpretation, however, is that Brien *et al* are hinting at *complementarity between remedy and consultation*. Thus, RCTs which emphasise the medicine might *necessarily* lose sight of the consultation; while RCTs emphasising the consultation (e.g., Brien *et al*) might *necessarily* lose sight of the medicine.

**Conclusion:** The Brien *et al* trial is too underpowered to draw firm conclusions as to whether homeopathy's effects are due solely to the consultation, or a complementary relationship with the remedy. However, by implying the power of the homeopathic consultation, Brien *et al* might have begun to reveal how RCTs allow knowledge of the therapeutic process EITHER to the medicine OR the consultation, *but not BOTH with absolute certainty at the same time*.<sup>4</sup> This biomedical re-statement of Heisenberg's Uncertainty Principle<sup>8</sup> suggests all that RCTs can reveal is that the therapeutic process is comprised of complementary parts of a whole real-life integrated phenomenon: not just in homeopathy, but for all healing modalities, including conventional medicine.

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## Modeling entelexy: quantized gyroscopic rotation as a metaphor for the vital force (vf) in homeopathy

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Integrative healthcare assumes that for the sake of our patients, conventional and complementary and alternative medicine (CAM, in all its forms, including homeopathy) find some common ground. The problem however, is that conventional medicine (CM) is dominated by scientism, relentless reductionism, and a purely mechanistic epistemology.<sup>1</sup> Thus, only physical manifestations of dis-ease are considered 'real', as they are observable to the senses.

Homeopathy/CAMs adopt a more holistic epistemology, embracing the ancient notion of entelexy: that an essentially embodied but non-physical (and therefore not directly observable) Vital Force propels an organism towards self-fulfillment, e.g., health.

One way to meld these opposing epistemologies is to model entelexy using the multi-dimensional *discourse* of quantum theory. This is because, "... it is possible for quantum properties (e.g., a particle's wave function) to be physical but not directly observable or measurable".<sup>2</sup> Also, "a wave function contains within it all that can possibly be known about a system by observation, not its ontological reality, separate from the observer."<sup>2</sup> Based on these insights, I propose a metaphor for the Vital Force (Vf) as a multi-dimensional quantized gyroscope, exhibiting symptoms in our reality (and therefore physical but not directly observable) only when it 'precesses'.<sup>3</sup>

Elaborating the metaphor further, diseases and remedies are envisaged as 'torque-like' vectors that, respectively, 'brake' or 'accelerate' the quantized Vf gyroscope's rate of spin. The former causes the Vf to 'precess,' eliciting symptoms in our reality: the latter corrects precession by accelerating the Vf, which 'throws off' the dis-ease and restores health. The metaphor also illustrates a mirror-like relationship between dis-eases and homeopathic remedies (e.g., Hahnemann's description of remedies as similar 'diseases'),<sup>4</sup> and suggests CM's homeostatic immune system might be seen as an embodied projection of homeopathy's Vf.<sup>5, 6</sup>

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## Usage and appraisal of educational media by homeopathic therapists – A cross sectional survey

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### Background:

During recent years the market for homeopathic education media has increasingly diversified with old (books, seminars) and new media (video-seminars, pc-programs, homeo-wiki and internet-courses). However, little is known about homeopaths' preferences in using educational media and their requirements of this topic.

### Aim:

This survey was designed to gain a better understanding of the usage and appraisal of educational media by homeopaths.

### Methods:

192 homeopathic practitioners (GPs and health practitioners) at a educational conference were asked to answer a standardized questionnaire covering the topics "formal education and context of work" (9 items), "homeopathic practise and usage (24 items), "utilization of educational media" (9 items) and "favoured attributes for educational media" (11 items).

### Results:

Out of 192 homeopaths who attended the conference, 118 completed the questionnaire (response rate 61.5 %). For their continuing homeopathic education they predominantly indicated to use books (scale value from 0=never to 2=always: 1.72) and seminars (1.54) whereas journals (0.98) and the internet (0.65) were used less often. The most favoured attributes concerning medical education media were reliability (1.76), relevance for clinical practice (1.74) and user friendliness (1.6). Less favoured attributes were inexpensiveness (1.1), graphical material (0.92) and interactivity (0.88).

Conclusions:

The survey illustrates the current situation of medical education media in homeopathy. Although there are parallels to earlier research conducted in conventional GPs, homeopaths are more likely to refer to classical media. New education tools should be designed according to these preferences.

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Handelsregister des Amtsgerichts Bochum Nr. HRB 8671

**Acceptance of homeopathy by the staff of an intensive care unit: A service evaluation**

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Background: Although intensive care medicine relies mainly on mechanical interventions, technical devices and intensive drug treatment, initial experience demonstrated that additional homeopathic treatment may be helpful in these patients as well. We examined the acceptance of homeopathic treatment in the personnel of an intensive care unit (ICU).

Methods: The entire crew of the ICU of a Swiss hospital was asked to fill in a self-administered questionnaire.

Results: The response rate was 42% (13 of 31 persons). 58% were female. 73% of the participants were in the age group between 31 and 50 years. All participants had previous experiences with homeopathy (50% were treated with homeopathic drugs, 28% consulted a homeopath, 17% consulted a physician with homeopathic training and 5% took basic courses in homeopathy).

30% opted for the use of homeopathy on the ICU, 17 voted against it, whereas 50% were inconclusive.

67% wanted to get additional information about the use of homeopathy on an ICU.

Conclusion: Our results demonstrate that merely a minority rejects the additional use of homeopathy on an ICU. Half of the participants were inconclusive, which is at least partly due to the lack of information about homeopathy. As a consequence, more than two thirds were interested in additional information concerning the use of homeopathy on the ICU, not for personal use. Based on the results of our survey, ICU personnel seem to regard homeopathy as a therapeutic option in their daily work, but they do not receive adequate support. In conclusion, the subject of homeopathy should be included in the specialized training of ICU personnel.

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## Exploring the effectiveness of homeopathic treatment for irritable bowel syndrome

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**Aims:** This study had two aims: to explore the effectiveness of homeopathic treatment compared to usual care, and to investigate the feasibility of carrying out a study comparing homeopathic treatment to an attention control

**Background:** Irritable bowel syndrome is a common chronic complaint which has a significant impact on people's quality of life. Despite much research there is no consensus on the optimal treatment for IBS and prognosis for recovery is poor. It is therefore not surprising that people with irritable bowel syndrome seek homeopathic treatment, with gastroenterological problems being the fourth most common reason for referrals to NHS homeopathic hospitals. However there is no clear evidence regarding the effectiveness of individualised (classical) homeopathic treatment in the treatment of irritable bowel syndrome.

**Methods:** This study involved a three armed randomised controlled trial of individualised homeopathic treatment compared to an attention control and usual care. An attention control is a treatment designed to control for the time and attention given to the patient by the therapist, in this case the attention control chosen was supportive listening. An attention control arm was included in this study to test the feasibility of including an attention control in a trial of individualised homeopathic treatment.

This presentation will consider the challenges in carrying out a study that explores the effectiveness of homeopathic treatment in an NHS setting. The challenges to carrying out such a study and how they were overcome will be discussed. In addition, the rationale behind the choice of methods, and why supportive listening was chosen as an attention control will be considered.

Initial findings from trial will be drawn on to examine whether or not supportive listening is an appropriate attention control for homeopathic treatment.

**Homeopathic treatment against Candida among a diverse population including children and adults, diagnosed on the autistic spectrum. A retrospective study**

Prof. Israela Berdicevsky\*, Dr. Boaz Ron, Mr. Danny Dushan Ron

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Experimental: Feces samples and vaginal swabs were sent to a private microbiological laboratory under the guidance of Dr. Eli Lefler (a senior microbiology Ph.D and a senior mycologist with huge experience in the field) and Mr. Doron Shefei. The laboratory is located at Elisha hospital in Haifa. The samples were sent to the laboratory and the results were evaluated quantitatively due to the insolvency growth of Candida as follows: negative, weak, middle, massive, massive plus. If the results were positive a homeopathic mixture was prepared individually (at the homeopathic pharmacy of Super-Pharm). The individuals were asked to take the mixture for three months. At the end of this period, all the patients had to send again stool for cultivation for presence of Candida. The patients were asked to keep their regular kind of nutrition.

Results:

Presence of Candida	Before treatment	After treatment			
		Negative (0)	Weak (1)	Medium (2)	Massive (3)
Massive (+) (4)	21	10	2	6	3
Massive (3)	8	3	3	2	
Medium (2)	4	3		1	
Weak (1)	3	3			
Negative (0)	0	0			
Summary of tested samples	36	19	5	9	3

No. sample tested	The difference among the samples	% of total samples
13 samples	Massive or massive positive – to negative	36.1%
6 samples	Medium or weak – to negative	16.7%
14 samples	Decreasing in one level or more, without turning into negative	38.8%
4 samples	Didn't react to the treatment and stayed the same level	11.1%

**33 (91.7%) samples out of 36 showed improvement due to treatment.**

Conclusions: From the table it can be concluded that 36.1% of the samples that showed massive and massive plus presence of Candida before, after the homeopathic treatment, became negative whereas 11% of the samples did not responded at all. 16.7% of the stool samples that showed low concentrations became also negative. More than 91% of the samples showed improvement after treatment.

Summary: Due to these results it can be concluded that this homeopathic treatment against Candida is highly efficient. This is very important especially among the autistic population, in which Candida is widespread and difficult to treat. I want to emphasis that I know personally some children that were treated successfully.

## Homeopathic potencies alter photosynthesis of cowpea

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The effect of potentized CCC and potentized maleic hydrazide (MH), a growth retardant was studied on the growth of cowpea. We studied further to see whether CCC 30 prepared with nano particles was more effective than the usual CCC 30. CCC 30, CCC 200, MH 30 and ethanol 30 (control) were prepared by the standard procedure of successive dilution (1:100) followed by succussion. CCC 30 (nano) was prepared by initially triturating CCC with copper nano particles. The triturated material was later diluted and succussed following the standard procedure. Ethanol 30, prepared in the same way, was used as the control. Plants grown in earthen pots were treated separately with each of the test potencies by foliar spray. The application was repeated seven times. All the treatments significantly increased plant growth, chlorophyll, sugar and protein in the leaves. CCC 30 (nano) and CCC 200 were more effective than CCC 30. Of the four agents MH 30 induced mamum protein synthesis in the leaves.

**Clinical evaluation of the effects of Arnicare Gel, a homeopathic preparation in sport related pain and stiffness****The efficacy and safety of a homeopathic arnica gel (Arnicare®) in the treatment of sports**

Sion Nobel, M.D., Merville Christophe Pharm. D, Christopher Baker, Fayard Anne-Laure Pharm. D., [Terzan Laurence M.D](#)

*Objective:* To evaluate the efficacy and safety of a homeopathic arnica gel (Arnicare®) in the treatment of sports related muscular soreness and pain.

*Design:* Randomized, double blind, placebo controlled clinical trial

*Setting:* Self use of an over-the-counter preparation by athletes participating in a club sport activity.

*Subjects:* Moderately trained athletes who experienced pain and stiffness after competitive sports games.

*Interventions:* Arnicare®, a homeopathic gel containing 7% arnica montana 1X, or matching placebo, applied to the lower extremities 3 times daily shortly before and after sports games until resolution of symptoms.

*Main outcome measures:* Pain and stiffness at different time points as assessed on a 100mm visual analogue scale after in total three sports games.

*Results:* 120 subjects (54 males, 66 females) were enrolled and randomized into two groups of 60. Subjects were mainly basketball players (85%) and the groups were comparable at baseline. The overall (baseline adjusted) level of stiffness during the 72 hours following the sports game was significantly less in the Arnicare group as compared to the placebo group (23.7mm versus 29.1mm,  $P=0.02$ ). With regard to the overall level of pain there was a similar trend that did not reach statistical significance (24.9mm versus 27.9mm,  $P=0.17$ ). Between group differences were most pronounced 12-36 hours post-exercise. 2 subjects in the arnica group experienced mild side effects (slight tingling, itching) that did not lead to discontinuation of the treatment.

*Conclusions:* Arnicare® gel can be used after sports activities to help with the short term effects of exercise stiffness and pain, as a substitute for OTC analgesic and anti-inflammatory drugs: very few subjects used any analgesic in conjunction with Arnicare® gel. Furthermore, Arnicare® gel was safe in use.

## Effects of homeopathic treatments on strawberry plants in field

Grazia Trebbi<sup>1\*</sup>, Giovanni Dinelli<sup>1</sup>, Ilaria Marotti<sup>1</sup>, Valeria Bregola<sup>1</sup>, Alessandro Benni<sup>1</sup>, Lucietta Betti<sup>1</sup>

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In conventional agriculture strawberry plants are generally treated with fungicides to control pathogens. However, consumer concerns about possible risks associated with the use of fungicides, along with development of pathogen resistance, have resulted in an intensive search for safer, more effective control options that pose minimal risk to human health and the environment. One of them could be the use of homeopathic treatments, that, thank to their extreme dilution level, do not lead to any toxicity or accumulation in the environment (Mader *et al.*, 2002).

The present research aimed at verifying the efficacy of such treatments on strawberry plants by evaluating phytopathological (control of infection induced by the fungus *Botrytis cinerea*, one of the most common pathogen of this crop), agronomical (fruit production) and biochemical (antioxidant activity, polyphenols and flavonoids) parameters. We performed three subsequent field trials (in 2010, 2011 and 2012) at a biodynamic farm: in all trials, the field was divided in plots consisting of 18 plants/treatment, each treatment being replicated 4 times in a randomized complete block design. Homeopathic treatments were chosen on the basis of previous experimentation in growth chamber in which they gave significant results in the control of *B. cinerea* infection. They were *Sulphur 6x*, *Horn-equisetum 6x* and *Sulphur 6x + Horn-equisetum 6x*, being ultra pure water as a control. These treatments were sprayed weekly according to biodynamic calendar from about the end of March to the mid-June; assessments were performed weekly on fruit production and infection level. At the end of trials, strawberry samples were collected for biochemical analyses. Results showed that some homeopathic treatments induced a decrease of infection level and an increase of both strawberry production and biochemical compounds.

Data obtained from this experimentation need further confirmations by performing field trials in other location and/or by using other crops, but can provide first indications for selecting homeopathic treatments to be proposed for practical use in agriculture, in the context of the so called “agro-homeopathy”.

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**References:** Mäder P, Fließbach A, Dubois D, Gunst L, Fried P, Niggli U 2002 Soil fertility in organic farming. *Science* 296: 1694-1607.

**Depressed patients treated by homeopaths: A protocol for a pragmatic randomized controlled trial and qualitative study applying the cmRCT design**

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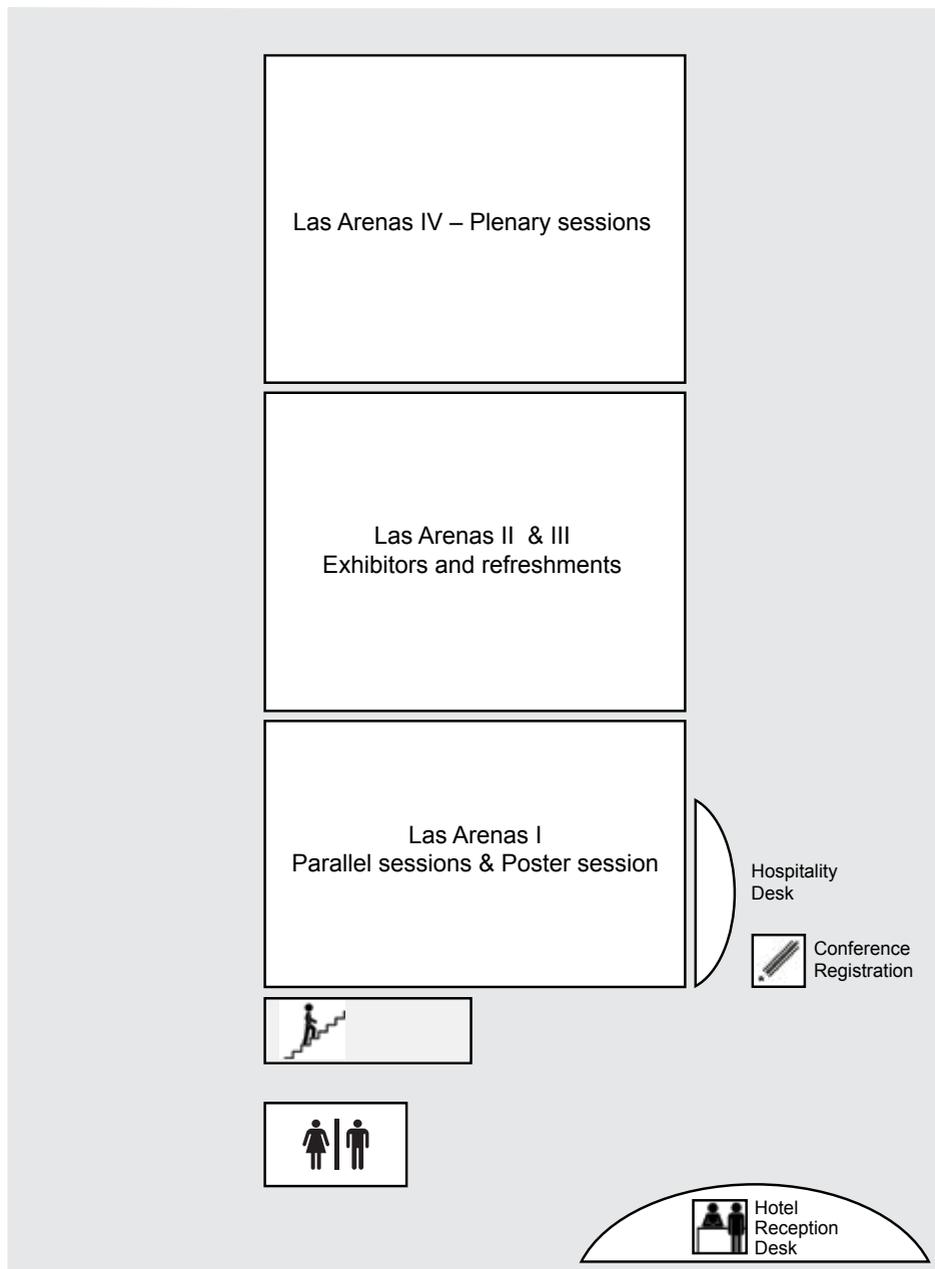
**Context:** Depression is a major healthcare problem in Europe and worldwide. The WHO predicts depression will become the main burden of disease worldwide by 2030. Established treatments (antidepressants and the 'talking therapies') may help many depressed patients, but not all. Antidepressants are known to cause unwanted side-effects and many patients refuse to take such drugs. Depression is one of the main reasons why patients seek homeopathic treatment. Existing evidence of the effectiveness of homeopathy in depression is limited and former studies have struggled with difficulties such as low recruitment rates. Qualitative studies reporting on depressed patients' experiences with homeopathic treatment have not previously been published.

**Aims:** To evaluate the acceptability and comparative clinical and cost effectiveness of adjunctive treatment provided by homeopaths for patients with self-reported depression in addition to usual care, as well as patients' experiences with homeopathic treatment.

**Methodology:** We propose to carry out a pragmatic randomised controlled trial using the 'cohort multiple' randomised controlled trials (cmRCT) design. The pragmatic design has been chosen in order to increase external validity. Patients will be recruited from the South Yorkshire Cohort (SYC) which includes some 20 000 participants, of which about 9% suffer from self-reported long-standing depression. By using this methodological approach we hope to facilitate the recruitment process, increase recruitment rates and reduce attrition rates. Patients will be treated by homeopaths over a 9 month period and will be assessed over a period of 12 months. The main outcome measure will be PHQ-9 at 6 months. Secondary outcomes will include PHQ-9 at 12 months, and at 6 and 12 months: GAD-7, EQ-5D, BMI, MYMOP2 and a life satisfaction score. Inclusion/exclusion criteria will be as open as possible, in order for treatment to be as similar to 'real world practice' as possible. We will also be assessing patients' experiences through semi-structured interviews with a purposive sample of participants receiving treatment by a homeopath. We report preliminary data including response rates and, if possible, uptake of intervention rates.

# Notes

# Venue Plan



# Thursday

18:00 – 20:00 Registration

# Friday

08:00 Registration opens

Las Arenas IV — Plenary Session

09:00 — 09:30 **Opening Ceremony**

09:30 — 10:30 **Homeopathy Research**

9.30 ..... Dr Peter Fisher

10.00 ..... Dr Stephan Baumgartner

Las Arenas IV — Parallel Session

11:00 — 12:20 **Pathogenetic trials & Clinical research**

11.00 ..... Jeremy Sherr

11.20 ..... Alastair Gray

11.40 ..... Dr José Enrique Eizayaga

12.00 ..... Dr Lex Rutten

Las Arenas I — Parallel Session

11:00 — 12:20 **Experimental Research**

11.00 ..... Dr Giovanni Dinelli

11.20 ..... Dr Tim Jäger

11.40 ..... Dr Maria Olga Kokornaczyk

12.00 ..... Dr Miek Jong

Las Arenas IV — Plenary Session

14:00 — 15:20 **Health economics & Clinical research**

14.00 ..... Dr Elizabeth Thompson

14.30 ..... Petter Viksveen

15.00 ..... Dr Laurence Terzan

Las Arenas IV — Plenary Session

15:50 — 16:50 **Poster Talks**

15.50 ..... Dr Theodoros Lilas

16.00 ..... Dr Lionel Milgrom

16.10 ..... Dr Susanne

Pannek-Rademacher

16.20 ..... Dr Laurence Terzan

16.30 ..... Dr Joyce Frye

16.40 ..... Miranda Castro

Las Arenas I

17:00 — 19:00 **Poster Session**

19:30 **Evening Excursion into Barcelona City Centre**

# Saturday

## Las Arenas IV — Plenary Session

- 09:00 — 10:20 **Research Theory & Clinical Research**  
 09.00 .....Dr Robert Mathie  
 09.20 .....Dr Sofia Wenna  
 09.40 ..... Prof Jürgen Pannek  
 10.00 .....Dr Christien Klein-Laansma

## Las Arenas IV — Plenary Session

- 10:50 — 12:30 **Laboratory Studies, Veterinary & Ethics**  
 10:50 .....Prof Thomas Ostermann  
 11.10 ..... Dr Debora Olioso  
 11.30 ..... Dr Ghada Alsaleh  
 11.50 ..... David Eyles  
 12.10 .....Dr Delny Britton

## Las Arenas IV — Parallel Session

- 14:00 — 15:20 **Experimental Research**  
 14.00 .....Prof Christian Endler  
 14.40 .....Prof Leoni Villano Bonamin  
 15.20..... Dr Yakov Freed

## Las Arenas I — Parallel Session

- 14:00 — 15:20 **Qualitative & Clinical Research**  
 14.00 ..... Dr Gualberto Diaz-Saez  
 14.20 .....Dr Ramona Jurcau  
 14.40 .....Dr Shaik Shamsur Rahman  
 15.00..... Petra Klement

## Las Arenas IV — Plenary Session

- 15:50 — 17:10 **Fundamental Research**  
 15.50 .....Prof Iris Bell  
 16.30 ..... Dr Alexander Tournier  
 16.50 .....Dr Steven Cartwright  
 20:00..... **Gala Dinner**

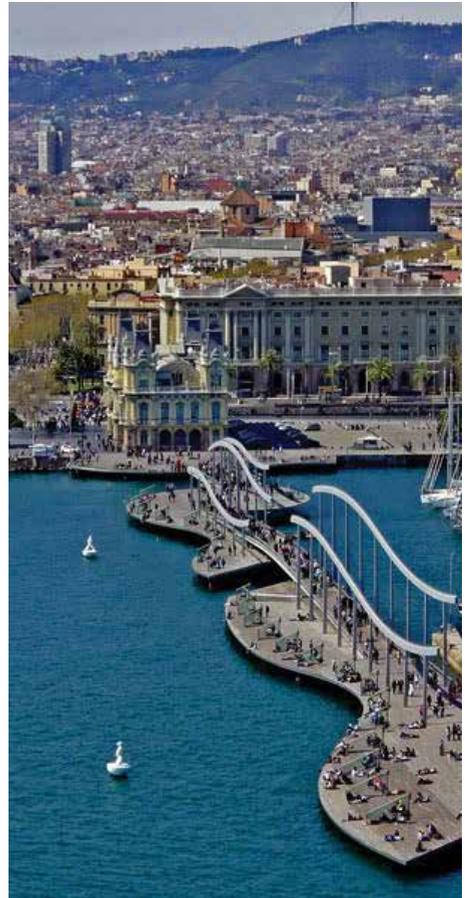
# Sunday

## Las Arenas IV — Plenary Session

- 09:10 — 10:30 **Clinical Research**  
 09.10 ..... Dr Elio Rossi  
 09.50 .....Dr David Brule  
 10.10 ..... Philippa Fibert

## Las Arenas IV — Plenary Session

- 11:00 – 12.20 **Homeoprophylaxis**  
 11.00 .....Prof Gustavo Bracho  
 11.40 .....Dr Sandra Salles  
 12.00 .....Dr Gadugu Srinivasulu  
 12:20 – 12:30..... **Closing ceremony**





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