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-build 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 and drug prescription in a primary care setting shows high potential for homeopathy

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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.

***Keywords:*** anxiety, homeopathy, epidemiology, primary care.

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

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***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

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***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