

economic model of vaccine programs has far-reaching effects for both global health and economic sustainability.

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

Kimberlee Blyden-Taylor

E-mail: [KBlyden-Taylor@ccnm.edu](mailto:KBlyden-Taylor@ccnm.edu) (K. Blyden-Taylor)

**Introduction:** Diagnosis of bipolar spectrum disorders (BSD) has substantially expanded in scope due to changing diagnostic criteria. As a result, the societal impact of these disorders has garnered greater public awareness and concern. The aim of this paper is to identify evidence in regards to individualised homeopathic treatment of patients with symptoms of BSD.

**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 BSD exclusively include documentation of single cases presented as informal abbreviated interviews or as summaries. 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. 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.

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

David Brulé<sup>1,\*</sup> and Dugald Seely<sup>2</sup>

<sup>1</sup>Riverdale Homeopathic Clinic, Toronto, Canada

<sup>2</sup>Ottawa Integrative Cancer Centre, Ottawa, Canada

\*Corresponding author.

E-mail: [david@rhronline.ca](mailto:david@rhronline.ca) (D. Brulé)

**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.