



# The placebo effect and its ramifications for clinical practice and research. Villa La Collina at Lake Como, Italy, 4–6 May 2012

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## KEYWORDS

Placebo;  
Placebo effect;  
Placebo response;  
Context effects;  
Empathy

## Summary

*Introduction:* The purpose of this workshop was to further explore the implications of the placebo effect for both research and clinical practice from a variety of angles with a group of selected experts.

*Method/approach:* The use of placebos in both clinical practice and research was explored in depth from a historical, methodological, ethical, legal and cultural point of view. The current state of knowledge regarding the placebo effect was established, knowledge gaps were identified, and the implications for both clinical research and practice were discussed in depth. *Key messages:* • Placebos have been consciously used in clinical practice since the 18th century, but only emerged as a research topic in the western world in the second half of the 20th century.

- The placebo *response* consists of the placebo *effect* plus the natural course of the disease, and is a meaningful part of all medical treatments.

- A variety of not fully understood individual, context and cultural factors contribute to the placebo response and interact in a non-linear way with the specific effects of medicines.

- The assessment of a therapeutic effect in placebo-controlled RCTs is often difficult due to a strong placebo response, e.g. in Central Nervous System (CNS) indications like major depression or in Irritable Bowel Syndrome.

- Placebo effects occur, and can affect the validity and appropriateness of placebo controlled trials in conventional as well as Complementary and Alternative Medicine (CAM) research.

- It may be impossible to fully disentangle the verum and sham effects of both CAM and conventional medical procedures such as for instance acupuncture and surgery.

- Context/meaning effects, including doctor empathy, are highly relevant and under-researched in both conventional and complementary medicine.

- The use of 'impure placebos' (non-indicated/ineffective medicines) in clinical practice may be common, but little reliable data is available due to complexities around the definition of impure placebos and underreporting.

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- The assumption that placebo effects do not occur in veterinary research is likely to be incorrect, e.g. owner empathy and vet expectations can affect outcomes.
- Various innovative trial designs that better deal with the placebo issue are available, but only as partial solutions.
- Patient treatment will benefit from better understanding and appropriately utilising meaning/context effects.

*Conclusions:* There are many remaining knowledge gaps with regard to the placebo response. The evolving knowledge challenges the paradigm of the placebo controlled RCT as a gold standard for demonstrating benefit of treatments. There are a number of pointers towards alternative research designs and paradigms worthy of further exploration. The evolving knowledge can contribute to the further development of a 'meaning orientated' and patient centred healthcare system.

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## Presenters

- Dr. Jürgen Clausen, Karl and Veronica Carstens Foundation, Germany
- Prof. Paul Dieppe, Pensula Medical School, Universities of Plymouth and Exeter, UK
- Prof. Paul Enck, University of Tübingen, Germany
- Dr. Christian Fidelak, bovicare GmbH, Germany
- Prof. Robert Jütte, Institute for History of Medicine, Germany
- Prof. Irvin Kirsch, University of Hull, UK/Harvard Medical School, USA
- Prof. Klaus Linde, Technical University of Munich, Germany
- Dr. Stewart Mercer, University of Glasgow, United Kingdom
- Prof. Daniel Moerman, University of Michigan, USA
- Dr. Clare Relton, York University, United Kingdom
- Prof. Dr. Claudia Witt, Charité University Medical Centre, Germany

## Invited participants

- Dr. Wolfgang Berger, Heel GmbH, Germany
- Mr. Max Daege, Gesellschaft für Pluralismus in der Medizin e.V., Germany
- Prof. Dr. Brigitte Tag, University of Zürich, Switzerland
- Prof. Dr. Eckhart Hahn, University of Oldenburg, Germany
- Dr. Robbert van Haselen, Editor-in-Chief, Complementary Therapies in Medicine, United Kingdom
- Dr. Jörg Zinserling, Federal Institute for Drugs and Medical Devices (BfArM), Germany

## Introduction

The event took place in the wonderful setting of the shores of Lake Como, in the former German chancellor's (Konrad Adenauer) favourite holiday resort. This provided an ideal and informal setting for the event which was attended by a small but broad and multidisciplinary mix of invited experts. The host and main organiser of the conference was Prof. Robert Jütte, the principal author of a recent report on the role of placebo in medicine.

The aim was to assemble experts in a discussion around the topic of placebo from both the conventional and CAM

community. It was not intended to be 'just another' conference on the topic of the biology and/or psychology of placebo effects. For instance, the participants included researchers who conducted or reviewed placebo controlled research in veterinary medicine, as well as a leading academic expert on the role of empathy in clinical medicine. Also, experts critical of putting too much emphasis on the placebo controlled clinical trial as a research design, were invited. Some of the presentations and discussion focused on looking for innovative research designs that maintain the rigour of placebo controlled trials, whilst at the same time being more acceptable from an ethical and practical point of view. In the latter domain CAM researchers were able to contribute richly to the discussion because CAM disciplines have been relatively often confronted with the infeasibility or impossibility of conducting double blind, placebo controlled trials, e.g. acupuncture being a point in case. So the objective of the workshop was not only to look at the history and current state of play regarding knowledge on the placebo effect, but also to look at what 'lies beyond', including harnessing some of the lessons learnt from placebo research for the clinical benefit of the patient.

## Report on presentations

### Robert Jütte

#### Early history of the placebo

The word "placebo" originates from an ancient proverb where it was used with the meaning "to carry a favour". The term 'placebo' was coined by the English physician Alexander Sutherland in 1763 and further introduced into the medical language by the Scottish physician William Cullen in 1772. His placebo was not an inert substance, but, e.g. a low dose of medicine considered, from the physician's perspective, to be ineffective. In the German medical literature it would take until the second half of 20th century for the term to become more commonplace. Early uses of placebos in clinical practice were mainly driven by the motivation to satisfy the condition of the patient's mind, and not necessarily to achieve therapeutic effects.

Milk sugar was commonly used as placebo but alternatively the use of 'bread pills' (pills made of bread crumbs) was common and first reported in the 1780s.

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