**Reviewer's report**

**Title:** Introducing a new Concept to assess the Efficacy of psychopharmacological and psychotherapeutic Interventions in Patients with Major Depression

**Version:** 1  **Date:** 14 March 2012

**Reviewer:** Bruno Falissard

**Reviewer's report:**

This is a short conceptual paper which does not present some study results but instead suggestions to improve the usefulness of randomized controlled trials (RCT) in the field of depression (but these suggestions could be in fact applied also to many other therapeutic areas, included outside the field of psychiatry).

The subject is all the more important as we are indeed at a turning point in the process of evaluation of treatments, pharmacological or not. The points raised by the authors are definitely relevant and their suggestions for improvement are simple, easy to implement in practice and could improve the interest of RCT results.

**Major compulsory revision:**

My main reproach against the paper is that it is indeed too short for a conceptual paper. It touches the subject but do not tackle it.

A paper which deals with the question of the incompatibility of double blinded/placebo RCTs with real life clinical practice has first to explain why these double blinded/placebo RCTs are supposed to be inescapable. There are of course methodological reasons for that, but also sociological ones and even anthropological ones (for instance RCTs can be considered as a ritual which goal is to pacify the relationships between health authorities and pharmaceutic firms). These reasons make that it can be (at least this can be discussed) simply absurd to transpose straightforwardly these double blinded/placebo RCTs from the field of development of medications to the field of development of psychological treatments.

Moreover there is not only the questions of double blind and placebo which make problem. These trials are done in particular countries and this raises transcultural problems. They are done in selected centers and this hampers the generalisability of results. The randomization itself can interfere with the level of efficacy of a treatment (a patient which receives a psychoanalytic treatment after a randomization could be less involved in this treatment than the same patient who would have chosen it deliberately). And since there are nowadays methodological approaches that are serious alternative to randomization, RCT themselves are questionable, especially in the field of psychological treatment.

To sum up, the paper begins a promising discussion, proposes some interesting
elements of answer. But the reader has the unpleasant feeling that (perhaps) the most important problems are elsewhere.

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests.