Homeopathy for depression--DEP-HOM: study protocol for a randomized, partially double-blind, placebo controlled, four armed study.

Abstract:
Homeopathy is often sought by patients with depression. In classical homeopathy, the treatment consists of two main elements: the case history and the prescription of an individually selected homeopathic remedy. Previous data suggest that individualized homeopathic Q-potencies were not inferior to the antidepressant fluoxetine in a sample of patients with moderate to severe depression. However, the question remains whether individualized homeopathic Q-potencies and/or the type of the homeopathic case history have a specific therapeutical effect in acute depression as this has not yet been investigated. The study aims to assess the two components of individualized homeopathic treatment for acute depression, i.e., to investigate the specific effect of individualized Q-potencies versus placebo and to investigate the effect of different approaches to the homeopathic case history.

A randomized, partially double-blind, placebo-controlled, four-armed trial using a 2 x 2 factorial design with a six-week study duration per patient will be performed. 228 patients diagnosed with major depression (moderate episode) by a psychiatrist will be included. The primary endpoint is the total score on the 17-item Hamilton Depression Rating Scale after six weeks. Secondary end points are: Hamilton Depression Rating Scale...
total score after two and four weeks; response and remission rates, Beck Depression inventory total score, quality of life and safety at two, four and six weeks. Statistical analyses will be by intention-to-treat. The main endpoint will be analysed by a two-factorial analysis of covariance. Within this model generalized estimation equations will be used to estimate differences between verum and placebo, and between both types of case history. For the first time this study evaluates both the specific effect of homeopathic medicines and of a homeopathic case taking in patients with depression. It is an attempt to deal with the challenges of homeopathic research and the results might be useful information in the current discussion about the evidence on homeopathy ClinicalTrials.gov: NCT01178255.