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Homeopathy for Major Depressive Disorder: protocol for N-of-1 studies (HOMDD-1 Studies)

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Abstract

**Background:** Using the N-of-1 methodology, we will investigate the effectiveness and safety of a standardized homeopathy protocol in treating ten individual cases of major depression. **Patients:** Women and men at age over 18 years with a diagnosis of a Major Depressive Episode given by a psychiatrist, who have presented a therapeutic response (reduction ≥ 50% of the baseline depression score, kept for at least four weeks) during a prior open homeopathic treatment following the protocol of the sixth edition of the Organon, with or without concomitant use of psychotropic drugs. **Methods:** Interventions: individualized homeopathy following the same protocol, administered in a solution containing a globule of the fifty-millesimal potency diluted in 20 ml of 30% alcohol; placebo - a hydroalcoholic solution containing 20 ml of 30% alcohol, in the same posology as the individualized homeopathic medicine. **Crossover study:** the participant will go through three consecutive treatment blocks, with two random and masked treatment periods (A or B) each, corresponding to homeopathy or placebo. Treatment periods will have two, four, and eight weeks in the first, second, and third blocks, respectively. A clinically significant worsening (characterized by an augmentation in BDI inclusion score ≥ 30%) will result in the termination of participation in the study and resumption of the open treatment. Primary measure: behavior of the score of the Beck-II Depression Inventory (BDI-II), self-evaluated by participants at weeks 0-2-4-8-12-16-20-24-28 and analyzed throughout the study concerning homeopathy and placebo partitions. **Secondary measures:** score of the Clinical Global Impression Scale; mental and physical health scores assessed by the 12-Item Short-Form Health Survey; participant’s blind preference for treatment A or B at each block; clinical worsening and Adverse Events. The participant, assistant physician, evaluator, and statistician will remain blinded for the study treatments until the completion of the analysis of data from every participant.

**Key-words:** Homeopathy; Depression; N-of-1 studies.

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