

### HRI statement on retraction of Macías-Cortés' et al. 2015

# Inexplicable retraction of a rigorous clinical trial showing homeopathy works for depression raises serious concerns over abandonment of the scientific process

The <u>Macías-Cortés 2015 study</u> is a gold-standard placebo-controlled trial conducted in a research hospital which found both homeopathy and the anti-depressant fluoxetine to be effective treatments for women with menopausal depression.

On 23 April the *PLOS ONE* editors took the shocking decision to retract this high quality article from their journal, five years after publication, despite failing to provide any valid reasons for their actions.

As Dr Alexander Tournier, HRI Executive Director explains, "This is a truly disturbing development as it means the usual scientific process itself has collapsed. A small number of individuals have decided to wipe a trial from the scientific literature without giving a single legitimate reason. This is particularly shocking considering that the editor who originally approved the study for publication in 2015 was Professor Yiru Fang – an expert psychiatrist with close to 35 years' experience in the field of mental health, specialising in depression research."

The extreme step of retracting a paper is usually only taken for the most <u>serious breaches</u> of scientific procedure, such as fraudulent results or plagiarism.

By contrast, the editors have attempted to justify retraction of this study on the basis of strikingly minor or completely unjustified points i.e.:

1. Not enough information was given about the precise details of the homeopathic treatment used in the trial.

Usually any such concerns about 'insufficient reporting details' are simply highlighted by other researchers in critiques or (if considered to be particularly important), the author is asked to provide the missing information as a comment or appendix. The medical doctor who led this trial – Dr Emma del Carmen Macías-Cortés – offered this solution to the journal but bizarrely was denied.

2. The study design used was insufficient to rule out the possibility that improvement seen in patients given the homeopathic medicines was due to a placebo-effect.

This is absurd. The design used is <u>the</u> most rigorous available in conventional medical research for the express purpose of ruling out placebo effects i.e. a randomised, double-dummy, double-blind, placebo-controlled, three-armed study. To suggest that this is insufficient begs the question, exactly what design would the Editors have considered to be 'sufficient'?

## 3. Not enough information was provided about how patients were diagnosed, and the Editors question the reliability of those diagnoses.

Each diagnosis of Major Depressive Disorder (MDD) was made by two independent members of the research team – a medical doctor and a psychologist – using internationally recognised and validated checklists and symptom assessment tools. Questioning the ability of these experienced professionals to be able to make a reliable diagnosis is astonishing.

The editors have also commented that the fluoxetine treatment given during the trial was inappropriate because it was a fixed dose and only given for 6 weeks. This is incomprehensible. According to a Cochrane review of 171 studies on fluoxetine<sup>1</sup>, 42% of trials used a fixed dose and the most common duration was 6 weeks. The 20 mg daily dose of fluoxetine used in this trial is a typical starting dose used in clinical practice, and as the study found that it worked, clearly it *was* an appropriate treatment.

Dr Macías-Cortés explains the importance of the study for patients: "Our trial found that homeopathic medicines work just as well as the usual conventional treatment fluoxetine (known as Prozac) for moderate to severe menopausal depression. This means homeopathy could provide an effective alternative for women suffering from these debilitating symptoms, who either cannot take antidepressants, or prefer not to take anti-depressants because of unwanted side-effects. To see this trial being retracted for no valid reason is truly heart-breaking for the whole research team involved, as it ultimately means fewer patients will benefit from this effective treatment."

Any objective scientist who reads the Editors' explanatory <u>retraction notice</u> will see that not one of the alleged weaknesses in the Macías-Cortés 2015 study – even if proved to be genuine, which we strongly dispute – are legitimate grounds for retraction.

For all who believe in the scientific method, even those who are sceptical about homeopathy, this action by PLOS One's Editors will be judged as a flagrant breach of scientific protocol and nothing less than a threat to academic freedom.

Rachel Roberts, HRI Chief Executive adds, "This study's positive result, achieved under the strictest possible trial conditions available in conventional medical research, will surprise many people who are not familiar with homeopathy, but discrediting a study because the results are controversial goes against the most core scientific principles."

#### **Further information**

In this <u>interview</u>, <u>Dr Macías-Cortés</u> talks about the findings of her study and how homeopathy helps her patients struggling with severe-moderate depression and other menopause-related symptoms.

Dr Macías-Cortés' full presentation on this study at the HRI Malta 2017 conference can also be viewed <u>here</u>.

Contact info@hri-research.org.

#### Reference

1. Magni LR, Purgato M, Gastaldon C, Papola D, Furukawa TA, Cipriani A, Barbui C. (2013) Fluoxetine versus other types of pharmacotherapy for depression. Cochrane Database of Systematic Reviews 7: Art. No.: CD004185. pmid:24353997