Australian Doctor questions – response from lead authors, Dr Menachem Oberbaum and Dr RK Manchanda, on behalf of the research team.

Thank you for your email and for querying us about our paper, "Homoeopathy vs. conventional primary care in children during the first 24 months of life—a pragmatic randomised controlled trial."

It was indeed a novel study which was conducted in India between 2018–2021 at the Jeeyar Integrated Medical Services (JIMS) Hospital, Telangana, a reputed tertiary-care hospital that provides integrated patient-centric care, using homoeopathy and Ayurveda alongside conventional medicine.

The study was undertaken after due scientific and ethical approvals, registration in the Clinical Trial Registry of India, and was regularly monitored by the Central Council for Research in Homeopathy, Ministry of Ayush, Government of India.

The study evaluated homoeopathy as a therapeutic system—using conventional medicine as a safety back-up—rather than assessing a single drug or indication for managing common and troublesome childhood illnesses during the first 24 months of life.

Was the retraction justified?

We strongly believe the retraction was unjustified and all authors rejected the retraction.

The stated reason — absence of blinding and placebo control — was explicitly evident to reviewers and editors during submission and peer review process, and the manuscript was accepted after evaluation.

Study limitations, to which we freely admit, are discussed in detail within the manuscript.

No concerns were raised regarding trial/data integrity, fabrication, or ethical misconduct by the journal and rather the authors have been invited to re submit a revised manuscript addressing these "methodological concerns," which is however not possible retrospectively.

How the methodology could be considered scientific?

This design was chosen to overcome known limitations in performing head-to-head randomised controlled trials of homeopathic medications.

This is explained in detail in the introduction of the manuscript.

However, some of the critical points are as under:

The study was not a conventional drug-versus-drug trial, but a pragmatic attempt to document widely observed real-world homoeopathic practice in India, where nearly 300,000 practitioners routinely treat young children, often reducing antibiotic use for common illnesses.

These practitioners as a part of their educational training study conventional medical as well homoeopathic subjects.

Previous studies have similarly reported benefits in diarrhoea, upper respiratory infections, etc. and reduced antibiotic use. (i, ii, iii, iv, v, vi)

Our aim was to capture this experience using a scientifically robust and ethically appropriate design.

The study population—children from birth to 24 months—required exacting ethical considerations.

A placebo-controlled, blinded design was neither feasible nor ethical, in line with the World Medical Association's Declaration of Helsinki (vii), which advises testing new interventions against the best proven care.

This open-label, pragmatic RCT prioritised participant safety while maintaining scientific rigor and external validity.

Robust randomisation, predefined endpoints, clinical assessments by paediatrician, and blinded statistical analysis were followed to control bias.

Absence of blinding does not constitute a methodological flaw, and similar pragmatic RCTs are readily available in the medical literature.

It was presented as showing that outcomes for those who received homeopathy were better than those who received standard medical care but both arms of the trial received standard medical care. Does that not render the entire trial fundamentally flawed and, as such, should never have been published?

The criticism reflects a misunderstanding of the study design.

The two treatment arms were not exposed to the same interventions. Children allocated to the conventional arm received standard medical care for all health problems throughout the first two years of life.

Children allocated to the homeopathic arm were treated solely with homeopathy, with the sole exception of cases involving serious conditions, where conventional treatment was added as a rescue medicine for ethical reasons and as per the protocol.

Children in both study groups however were offered routine nutritional supplements like vitamin D, iron, and calcium etc.

All children completed India's Universal Immunisation Programme.

Therefore, it is incorrect to state that both arms received standard medical care.

Conventional treatment in the homeopathic arm was restricted to a small subset of severe cases and does not invalidate the randomized comparison.

What was your role in the study?

Dr Menachem Oberbaum, former head of the Centre for Integrative and Complementary Medicine, Shaare Zedek Medical Center in Israel and Dr RK Manchanda, a former director general on the Centre for Central Council for Research in Homeopathy, India, contributed from study conceptualisation to final submission.

Every author played specific roles which are detailed in the manuscript.

The allegations made by Dr Philips - what is your response?

Dr Philips, a hepatologist practicing in Kerala, India, is a notorious critic of traditional medicine practices (AYUSH), well known in India for his defamatory posts of these systems, including homeopathy.

His derogatory remarks against Ayurveda have led to legal actions against him, police summons and government warnings from the Ministry of Ayush.

Two of his papers concluding fatal liver injury by consumption of ayurvedic products were recently retracted in the years 2020 and 2024 *[Editor's note – see end of article below to read the response of Dr Philip's to these allegations]*.

The claims made by him are ungrounded in fact, intended only to create doubt about the study and defame homeopathy.

European Journal of Pediatrics, after prolonged review, raised no questions about the study's scientific integrity or ethical conduct, contrary to Dr Philips' claims.

The retraction note in verbatim is given below:

The Editor has retracted this article. Concerns were raised regarding the methodology as described in this article. Post publication review confirmed concerns regarding the absence of blinding and placebo controls, which in the view of the Editor may introduce significant bias in the interpretation of the data, results and conclusions, which cannot

be rectified by an erratum. The Editor therefore no longer has confidence in the reliability of this article. The authors have been invited to submit a revised manuscript that addresses these concerns.

The study was completed at the JIMS Hospital, Telangana where all the records are maintained as per institutional policy. All authors stand firmly behind the study methodology and findings.

We appreciate you contacting us before going public with this, and we caution against being an echo-chamber for slanderous and unbased claims.

Dr Menachem Oberbaum and Dr RK Manchanda (on behalf of the study team)

References supplied:

i) Jacobs J, Jonas WB, Jimenez-Perez M, Crothers D. Homeopathy for childhood diarrhea: combined results and meta-analysis from three randomized, controlled clinical trials. The Pediatric Infectious Disease Journal. 2003 Mar 1;22(3):229-34.

ii) Roberts ER, Mosley AJ, van der Werf ET, Tournier AL. The EPI3-LASER study: Real-world observational evidence for homeopathy from General Physicians in France. HRI Research Article. 2021(36).

iii) Grimaldi-Bensouda L, Bégaud B, Rossignol M, Avouac B, Lert F, Rouillon F, Bénichou J, Massol J, Duru G, Magnier AM, Abenhaim L. Management of upper respiratory tract infections by different medical practices, including homeopathy, and consumption of antibiotics in primary care: the EPI3 cohort study in France 2007–2008. PLOS One. 2014 Mar 19;9(3).

iv) Jacobs J, Jimenez LM, Malthouse S, Chapman E, Crothers D, Masuk M, Jonas WB. Homeopathic treatment of acute childhood diarrhea: results from a clinical trial in Nepal. The Journal of Alternative and Complementary Medicine. 2000 Apr 1;6(2):131-9.

v) Jacobs J, Jiminez LM, Gloyd S, Carares FE, Gaitan MP, Crothers D. Homoeopathic treatment of acute childhood diarrhoea: a randomized clinical trial in Nicaragua. British Homoeopathic Journal. 1993 Apr 1;82(2):83-6.

vi) Jacobs J, Springer DA, Crothers D. Homeopathic treatment of acute otitis media in children: a preliminary randomized placebo-controlled trial. The Pediatric Infectious Disease Journal. 2001 Feb 1;20(2):177-83.

vii) World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013 Nov 27;310(20):2191-4. doi: 10.1001/jama.2013.281053. PMID: 24141714

Editor's footnote: This is the response of Dr Philip's to the retraction claims: "None of my studies were retracted. The 2020 removal was due to Herbalife's legal threats, not scientific error.

"The alleged 2024 retraction is imaginary—just like the clinical benefits of homeopathy."