

## ORIGINAL PAPER

# Homeopathic medicines for prevention of influenza and acute respiratory tract infections in children: blind, randomized, placebo-controlled clinical trial

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**Background:** Influenza and its complications are common at all ages, especially in children. Vaccines and anti-influenza drugs aim to prevent it. Preventative approaches with favorable risk profiles should be considered for flu, particularly since the evidence of the efficacy of anti-viral drugs is debated.

**Methods:** This pragmatic clinical trial was conducted in the Brazilian Public Health System in Petrópolis (BPHSP) with children aged from 1 to 5 years old. The medications used were mainly selected based on *in vitro* experiments (InfluBio), and in successful qualitative clinical experiences (Homeopathic Complex). Following informed parental consent, subjects were randomly distributed, in a blind manner, to three experimental groups: Homeopathic Complex, Placebo, and InfluBio. BPHSP health agents collected flu and acute respiratory infection symptomatic episodes monthly following the established protocol. The number of these episodes was registered in one year (2009–2010).

**Results:** Out of the 600 children recruited, 445 (74.17%) completed the study (149: Homeopathic complex; 151: Placebo; 145: InfluBio). The number of flu and acute respiratory infection symptomatic episodes detected in this clinical trial was low; however, it was different between homeopathic groups and placebo ( $p < 0.001$ ). In the first year post-intervention, 46/151 (30.5%) of children in the placebo group developed 3 or more flu and acute respiratory infection episodes, while there was no episode in the group of 149 children who used Homeopathic Complex, and only 1 episode in the group of 145 (1%) children who received InfluBio.

**Conclusion:** These results suggested that the use of homeopathic medicines minimized the number of flu and acute respiratory infection symptomatic episodes in children, signaling that the homeopathic prophylactic potential should be investigated in further studies. *Homeopathy* (2015) ■, 1–7.

**Key words:** Influenza; Flu; Clinical trial; Homeopathic medicines

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Received 2 June 2014; revised 4 October 2014; accepted 6 February 2015

## Introduction

Influenza (flu) is a viral disease that affects between 5 and 15% of the world population every year. It is caused by influenza viruses and the main symptoms are: high fever, aching muscles, headache and severe malaise, non-productive cough, sore throat and rhinitis. The virus is transmitted from person to person via saliva, sneezing or droplets. Less frequently it is transmitted by contact with a surface that has the flu virus on it followed by contact with the mouth or nose. Influenza spreads rapidly in seasonal epidemics. Most infected people recover without any medical treatment, but in the very young, the elderly, and immune compromised individuals, influenza infection can lead to severe complications, such as pneumonia and death.<sup>1,2</sup> Acute respiratory illness is the most common clinical infection in childhood and the most frequent reason for children's visits to the pediatrician.<sup>3</sup>

The co-circulating H1N1 and H3N2 subtypes of influenza A viruses cause symptoms, such as: cough, breathlessness, fever, and sore throat.<sup>4,5</sup> These viruses have been the main causal agents of annual flu outbreaks occurring in different regions of the world, resulting in 3–5 million severe cases of the disease and 500,000 deaths per year.<sup>1</sup> Nowadays, there are many drugs that are currently prescribed in the treatment of influenza and acute respiratory infection symptoms, and some of these drugs act as neuraminidase inhibitors (oseltamivir and zanamivir) and M2 inhibitors (rimantadine and amantadine) in the treatment of human flu. Jackson *et al* (2010) did a systematic review to evaluate the prophylactic effect of these drugs, showing positive results; nevertheless, these authors signaled the need for further studies with specific populations, like the elderly and children.<sup>6</sup> In fact, Shun-Shin verified the existence of a post-exposure prophylaxis when neuraminidase inhibitors were used in pediatric patients. However it is important to evaluate the risk and the possible appearance of resistant virus strains.<sup>7</sup> Additionally, some studies indicate that the conventional drugs have some adverse effects like headaches, gastrointestinal events, nausea, vomiting and others.<sup>8,9,10</sup> Worrying aspects of these treatments are the rapid resistance acquired, which has been detected 2–3 days after the start of treatment, and the recommendation of not using them in children, especially because of the absence of published clinical trials done with children.<sup>11</sup> Besides, zanamivir is an inhaled dry powder, delivered by a specific device, requiring minimum child autonomy to use this medicine.

Recently, Jefferson & Doshi<sup>12</sup> published a systematic review of anti-influenza drugs, such as oseltamivir and zanamivir, in adults and children for the treatment and prevention of flu, without differences in mortality and complications after the use of such drugs. Besides, the authors detected several methodological shortcomings in clinical trials done with anti-influenza drugs in the last decades, and signaled the importance of full clinical studies to support the use of those drugs for the prevention of flu and its complications, such as pneumonia.<sup>12</sup> Among others, these aspects shall stimulate the development of

new drugs for the treatment of influenza and its complications.

Flu epidemics and pandemics caused by H1N1, H2N2 and H3N2 subtypes of influenza A viruses have been responsible for diseases that take devastating proportions.<sup>13–16</sup> During the 20th century, four flu pandemics occurred, causing 50 million (Spanish, 1918–19), 2–4 million (Asian, 1956), 1–2 million (Hong-Kong, 1968) and 0.7 million (Russian, 1977–78) estimated deaths. The first flu pandemic in the 21st century, also known as swine flu, had as its etiological agent influenza virus A H1N1 and caused nearly 17,000 deaths.<sup>16</sup> This viral subtype still causes death in some countries.

Homeopathic medicines can be prepared from biological materials containing microorganisms, such as viruses and bacteria. Biotherapies are included in this category as remedies prepared from biological products following homeopathic procedures.<sup>17</sup> These medicines can be used to treat infectious diseases with known etiology.

In Brazil, the homeopathic physician Roberto Costa developed a biotherapy using living infectious microorganisms as etiological agents,<sup>18</sup> called "living nosodes". These clinical results motivated a study, using Roberto Costa's methodology, to verify the *in vitro* effects of a living nosode prepared from infectious influenza A virus (A/Aichi/2/68 H3N2 strain).<sup>19</sup> The results obtained from this *in vitro* study showed that this homeopathic medicine presented a stimulatory effect on J774.G8 macrophage cells, inducing an increase in the release of tumor necrosis factor [TNF- $\alpha$ ]. These promising *in vitro* results motivated the present clinical trial, developed from the same subtype of H3N2 influenza virus A (A/Victoria/3/75), and conducted in the Brazilian Public Health System (Rio de Janeiro, Brazil), comprising a significant number of children.

In Brazil, homeopathy was incorporated in the Public Health Service, through the National Policy on Complementary and Integrative Practices of the Health Ministry, published in 2006.<sup>20</sup> Since then, several different initiatives have been observed in several Brazilian Public Health Hospitals, including the city of Petrópolis, (Rio de Janeiro state). Petrópolis was one of the first cities in Brazil to implement homeopathy in the Public Health System. These experiences with an homeopathic complex consisting of bacterial strains (*Streptococcus* and *Staphylococcus*) and inactivated influenza virus, as tested in the clinical trial reported in this paper. But were not conducted by methods permitting evaluation of their efficacy. Most of these results are unpublished and were maintained as governmental records. This background motivated this clinical trial, using children from Petrópolis that belong to different public health sets.

The present clinical trial evaluated the prophylactic potential of homeopathy in children (1–5 years old) belonging to families from low economic and social classes who do not have access to the private health system and/or additional health care, at Petrópolis, Rio de Janeiro. Furthermore, Petrópolis is a mountain city with high humidity and low temperatures, climatic characteristics

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