

Calcium-vitamin D supplementation and Periodontal Therapy for Improving Metabolic and Inflammatory Profile among Pregnant Women: a feasibility trial (THE IMPROVE TRIAL)

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Project manager:	Amanda R Amorim Adegboye
Institution:	Division of Nutrition, Food & Public Health, Department of Life Science, University of Westminster, London
Collaborators:	Gilberto Kac, UFRJ, Brazil Berit L. Heitmann, Institute of Preventive Medicine, DK Michael Holick, Boston University, USA Michael Maia Schlüssel, University of Oxford, UK Paulo Nadanovsky, UERJ, Brazil Gustavo Lobato de Azevedo, IFF-FIOCRUZ, Brazil

Aim

The IMPROVE trial aims to assess the effect size, ability to recruit, and acceptability of a RCT for evaluating effectiveness and cost-effectiveness of a multi-component intervention for improving maternal metabolic and inflammatory status and oral health among low-income adult pregnant women with periodontitis in Rio de Janeiro (RJ), Brazil (BR).

Although our immediate goal is to improve maternal nutrition, oral and general health (metabolic and inflammatory profile), our ultimate goal is to reduce adverse gestational outcomes. Clarification of the procedures for setting up the study in such a way as to develop feasibility for the full trial will be ensured. Barriers and enablers vital to the integration of the proposed intervention into current health promotion programmes will also be assessed from the perspective of both local health service providers and study participants.

Description

The improvement of maternal and child health remains a key issue in global health. Production and improved accessibility of healthy and nutrient-rich milk-based products could potentially tackle health and nutrition inequalities in low-income countries.

This study will assess the acceptability of a multi-component intervention, including provision of calcium/vitamin-D fortified milk and periodontal therapy (PT), for improving maternal periodontal health and metabolic and inflammatory profiles. The IMPROVE trial is a feasibility randomised controlled trial (RCT) with parallel qualitative process evaluation. Our target population is low-income, pregnant, Brazilian women, with periodontitis, who have not seen a dentist in the last 6 months. A series of focus group discussions and interviews with the target population and with healthcare professionals will be conducted to identify key barriers and enablers to adoption and implementation of the intervention in family clinics in Rio de Janeiro. Participants will be allocated to 4 groups: 1) early PT plus fortified milk; 2) early PT plus plain milk; 3) delayed PT after delivery plus fortified milk; 4) delayed PT plus plain milk. The final results will contribute to the understanding of the significance of calcium and vitamin D, for short and long-term health and the occurrence of diseases, as well as to inform the current global debate on vitamin-D supplementation and fortification policy. The project will also include an education and training component for postgraduate nutrition students and family clinics' staff in addition to community empowerment.