



ORIGINAL ARTICLE

A randomized triple-masked controlled trial on the effects of synbiotics on inflammation markers in overweight children[☆]

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Received 19 March 2013; accepted 29 July 2013

Available online 30 October 2013

KEYWORDS

Synbiotic;
Children and adolescents;
Obesity;
Inflammation;
Trial

Abstract

Objective: the low degree of inflammation in obesity contributes to systemic metabolic dysfunction. Recent experimental studies proposed some effects of alteration in gut microbiota on inflammatory factors. This study aimed to assess the anti-inflammatory effects of a synbiotic supplement on inflammation markers in overweight and obese children and adolescents.

Methods: this randomized triple-masked controlled trial was conducted among 70 participants aged 6 to 18 years, with a body mass index (BMI) equal or higher than the 85th percentile. They were randomly assigned into two groups of equal number to receive synbiotic or placebo for eight weeks.

Results: fifty-six of 70 participants (80%) completed the study. Compared with the placebo group, the synbiotic group had significant decrease in mean values of tumor necrosis- α and interleukin-6, with significant increase in adiponectin; these changes were no longer significant after adjustment for BMI. There was no significant change in the mean values of high-sensitive C-reactive protein.

Conclusion: the present findings suggest the positive influence of synbiotic supplementation on inflammation factors, which are dependent to its effect on weight reduction in overweight and obese children.

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[☆] Please cite this article as: Kelishadi R, Farajian S, Safavi M, Mirlohi M, Hashemipour M. A randomized triple-masked controlled trial on the effects of synbiotics on inflammation markers in overweight children. J Pediatr (Rio J). 2014;90:161–8.

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PALAVRAS-CHAVE

Simbiótico;
Crianças e
adolescentes;
Obesidade;
Inflamação;
Ensaio clínico

Ensaio clínico controlado randomizado triplo-cego dos efeitos de simbióticos sobre marcadores de inflamação em crianças com sobrepeso

Resumo

Objetivo: o baixo grau de inflamação na obesidade contribui para disfunção metabólica sistêmica. Estudos experimentais recentes propuseram alguns efeitos de alteração na microbiota intestinal sobre fatores inflamatórios. O objetivo deste estudo foi avaliar os efeitos anti-inflamatórios de um suplemento simbiótico sobre marcadores de inflamação em crianças e adolescentes com sobrepeso e obesos.

Métodos: este ensaio clínico controlado randomizado triplo-cego foi conduzido entre 70 participantes com idade entre seis e 18 anos, com índice de massa corporal (IMC) igual ou acima do 85º percentil. Eles foram aleatoriamente divididos em dois grupos de igual número de participantes para receber simbiótico ou placebo por oito semanas.

Resultados: no todo, 56 de 70 participantes (80%) concluíram o estudo. Em comparação ao grupo placebo, o grupo simbiótico teve redução significativa nos valores médios de necrose tumoral- α e interleucina-6, com aumento significativo na adiponectina; essas alterações não eram mais expressivas após o ajuste do IMC. Não houve alteração importante nos valores médios da proteína C-reativa altamente sensível.

Conclusão: nossas conclusões sugerem a influência positiva da suplementação simbiótica sobre fatores inflamatórios, dependente de seu efeito sobre a redução de peso em crianças com sobrepeso e obesas.

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Introduction

The emerging global epidemic of obesity is a serious health problem at individual and public health levels. This is of special concern for the pediatric age group. Obesity is associated with chronic low-grade inflammation, which contributes to the systemic metabolic dysfunction linked to obesity-linked disorders, such as metabolic syndrome.¹

Increased expression and production of cytokines and acute phase reactants such as C-reactive protein (CRP), interleukins (ILs), tumor necrosis factor α (TNF- α), or lipopolysaccharides (LPS) result in the low degree of inflammation among obese individuals.^{2,3}

Some studies proposed that gut microbiota may participate in the whole-body metabolism by affecting energy balance, glucose metabolism, and low-grade inflammation associated with obesity and related metabolic disorders.⁴

It is documented that gut microbiota are different among obese and eutrophic individuals.^{5,6} Gut microbiota-derived LPS are known as a factor involved in the onset and progression of inflammation and metabolic disorders.⁷ LPS are a component of Gram-negative bacteria cell walls, which are among the most potent and well-studied inducers of inflammation.⁴

Moreover, any change in the gut microbiota may lead to change in the production of endotoxin and thus change in the LPS levels.^{7,8}

Although the intestinal epithelium acts as a continuous barrier to avoid LPS translocation, some events can damage this barrier. For instance, a study demonstrated that the modulation of gut bacteria following a high-fat diet strongly increased the intestinal permeability by reducing the expression of genes coding.⁹

Therefore, it can be assumed that regulating gut microbiota may be an appropriate strategy to control obesity and its related disorders.

Therefore, it was hypothesized that supplementation with synbiotics, which modulates gut microbiota and their production, may be effective in changing markers of inflammation in individuals with excess weight. This study aimed to investigate the effect of synbiotic supplementation on inflammatory factors in overweight and obese children and adolescents.

Method

The detailed methods of this study have been previously published;¹⁰ the findings on markers of inflammation, which have not been reported before, are presented here. The study was conducted from September to November of 2011 at the Isfahan University of Medical Sciences (IUMS), Isfahan, Iran. It was a randomized triple-blinded controlled trial, i.e. the researchers, participants and statistician were masked to the groups under study.

The trial protocol was in accordance with the Declaration of Helsinki, and was approved by the Research and Ethics Committee of IUMS. The trial was registered under trial registry code IRCT201103081434N4 at the national registry for clinical trials, which is a member of the World Health Organization.

After providing detailed information, an informed consent was signed by parents, and oral assent from participants was obtained.

Participants

70 apparently healthy children and adolescents, aged 6 to 18 years, with a body mass index (BMI) equal to or higher than the age- and gender-specific 85th revised percentiles of the Centers for Disease Control and Prevention,¹¹ which are in close agreement with the percentiles of Iranian children and adolescents,¹² were selected by random sampling

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