Clinical Nutrition 30 (2011) 156–164

Contents lists available at ScienceDirect

Clinical Nutrition

journal homepage: http://www.elsevier.com/locate/clnu

Original Article

Impact of dietary counselling and probiotic intervention on maternal anthropometric measurements during and after pregnancy: A randomized placebo-controlled trial☆

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ARTICLE INFO

Article history:
Received 21 December 2009
Accepted 26 September 2010

Keywords:
Dietary counselling
Probiotics
Pregnancy
Postpartum
Anthropometric measurements

SUMMARY

Background & aims: To establish whether probiotic supplemented dietary counselling influences maternal anthropometric measurements during and after pregnancy.
Methods: At the first trimester of pregnancy 256 women were randomly assigned to receive nutrition counselling to modify dietary intake according to current recommendations or as controls; dietary intervention groups were further randomized to receive probiotics *Lactobacillus rhamnosus GG* (ATCC 53103) and *Bifidobacterium lactis* (diet/probiotics) or placebo (diet/placebo) capsules in a double-blind manner, whilst the controls received placebo (control/placebo). The intervention lasted until the end of exclusive breastfeeding for up to six months.
Results: The risk of central adiposity defined as waist circumference 80 cm or more was lowered in women in the diet/probiotics group compared with the control/placebo group (OR 0.30, 95%CI 0.11–0.85, $p = 0.023$ adjusted for baseline BMI), whilst the diet/placebo group did not differ from the controls (OR 1.00, 95% CI 0.38–2.68, $p = 0.994$) at 6 months postpartum. The number needed to treat (NNT) with diet/probiotics to prevent one woman from developing a waist circumference of 80 cm or more was 4. Healthy eating pattern at 12 months postpartum ($p = 0.001$) and BMI prior to pregnancy ($p < 0.001$) were strong determinants of BMI at 12 months postpartum when adjusted for dietary intervention and exercise.
Conclusion: The impact of probiotics-supplemented dietary counselling on central adiposity, may offer a novel means for the prevention and management of obesity.
This trial was registered at clinicaltrials.gov as NCT 00167700, section 3.

1. Introduction

Balanced maternal nutrition during pregnancy ensures the physiological weight gain of the mother and thus the growth and development of the foetus. Recent evidence supports the programming theory, suggesting an impact of early nutrition on later risk of chronic life-style-related diseases: faster prenatal and postnatal growth has been associated with higher body mass index (BMI) in the child.[1] Explanations for the programming effect are being sought in both restrained and excessive dietary intake.

Interestingly, it is less widely acknowledged that nutrition during pregnancy influences maternal health both short- and long-term. An excessive weight gain during pregnancy predisposes to complications in both pregnancy and labour, while also exposing the mother to a heightened risk of obesity[2] and consequently obesity-related diseases in future years. Almost half of the female population are currently overweight, the problem often setting in after delivery of the first child.

Current attempts to prevent or manage obesity are based on the control of traditional life-style-related risk factors. Dietary changes such as a low-fat and fibre-rich diet may indeed be useful in weight control.[3] Pregnant women are particularly receptive to dietary counselling, as we have previously demonstrated.[4] An additional

☆ Conference presentation: Part of the work was presented in European Congress of Obesity, Amsterdam 2009.

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0261-5614/$ – see front matter
doi:10.1016/j.clnu.2010.09.009

means of weight control may be sought in modification of the gut microbiota. Recent advances in experimental and human studies suggest that the gut microbiota may be involved in fat accumulation, including excessive harvest and storage of nutrients. Microbiota deviations have been shown to associate with obesity,[5–9] the differences identified particularly in the proportions of Firmicutes and Bacteroidetes.[5–7,10] The normal-weight status in turn has been manifested with higher numbers of bifidobacteria[5,8,10] further supporting their immunomodulatory role beneficial for human health.[11] The possible mechanisms for the overweight regulating effect of microbiota arise as follows: the gut microbiota enables hydrolysis of indigestible polysaccharides to easily absorbable monosaccharides, and activation of lipoprotein lipase with consequent excessive storage of liver-derived triglycerides.[12] These processes boost weight gain, which may be counteracted by modification of the gut microbiota by probiotics,[13] with a potential to balance the low-grade inflammation associated with obesity.[14]

The present study targeted maternal diet and microbiota compositions to coordinate maternal and child metabolic, microbiological and immunological programming. In the combined intervention the objective was to establish whether dietary counselling and supplementation with a probiotic combination of *Lactobacillus rhamnosus* GG (ATCC53103) and *Bifidobacterium lactis* initiated in early pregnancy are effective in controlling the weight as well as the body composition of the mother during and after pregnancy.

2. Methods

2.1. Subjects

A cohort of 256 women were recruited to the study in the city of Turku and neighbouring areas in South-West Finland from April 2002 to November 2005. The women were informed of the study by leaflets outlining its aims and requirements, these being distributed during their first visit to a maternal welfare clinic. Interested recipients contacted the research nurse for information and an appointment at the study clinic in Turku University Hospital. Study eligibility required gestation at less than 17 weeks and no metabolic diseases such as diabetes. The study complied with the Declaration of Helsinki as revised in 2000. Written informed consent was obtained from the participants, and the study protocol was approved by the Ethics Committee of the Hospital District of South-West Finland.

2.2. Study design and intervention

At the first study visit, the baseline, which took place during the first trimester of pregnancy, background information concerning age, smoking, education, parity and pre-pregnancy weight was collected by interview. Subjects were randomly assigned to a prospective, parallel-group nutrition and probiotics intervention study with three groups (NCT00167700; section 3, http://www.clinicaltrials.gov). The randomization (Fig. 1) was conducted and the list generated by a statistician (TP) not involved in recruitment or study visits, according to computer-generated block randomization of six women to receive dietary counselling with probiotic capsules (diet/probiotics) or placebo (diet/placebo) and controls (control/placebo). Randomization to receive probiotics or placebo in the dietary intervention groups was conducted in double-blind manner and to receive placebo in the control group in single-blind manner. Sealed envelopes contained subject numbers corresponding to numbered probiotics and placebo containers and information on whether the subject would receive dietary counselling further to the standard counselling given in well-women

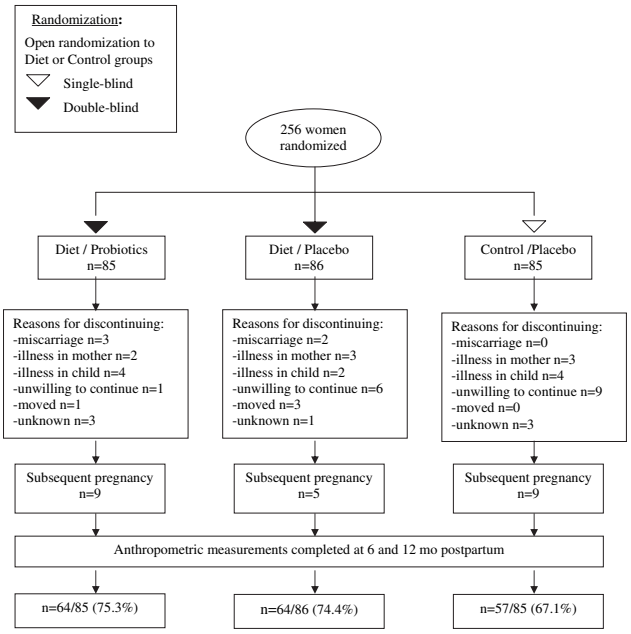

Fig. 1. Flow of participants through study.

clinics nationwide. The capsule containers were numbered according to the randomization list by an assistant not involved in the conduct or reporting of the study. At the first study visit the envelopes were opened by a research nurse and nutritionist in the presence of each study subject in their order of recruitment. The random allocation sequence was thus concealed until interventions were assigned. Research nurses and researchers ensured that capsules with corresponding numbers were given to the subjects and the appropriate dietary counselling intervention was carried out. The trial data were collected on printed case record forms and the members of the research group performed data entry. All data were kept confidential. The intervention code was not opened to researchers or nurses involved in the study visits. Staff in the hospital and well-women clinics was blinded to the intervention.

After baseline, the subsequent study visits took place at each trimester of pregnancy, and at one, six and 12 months postpartum. At each visit, the intervention groups received dietary counselling, supported by provision of food products for use at home and probiotics or placebo capsules. Food products and capsules were consumed from the first trimester of pregnancy until the end of exclusive breastfeeding, a maximum of 6 months postpartum. All pregnant women participating in the study also attended municipal well-women clinics.

Probiotics were administered as capsular preparations, one capsule per day, containing *L. rhamnosus* GG (ATCC 53103, Valio Ltd., Helsinki, Finland) and *B. lactis* 10^{10} cfu/d each (B. lactis Bb12, Christian Hansen A/S, Hoersholm, Denmark) and placebo in capsules containing microcrystalline cellulose and dextrose anhydrate (Chr. Hansen, Hoersholm, Denmark). Probiotics and placebo capsules and contents looked, smelled and tasted identical. Compliance in consumption was good, more than 95% of the subjects consuming the capsules and tolerating them well, 6% or less at the initiation of capsule consumption and 2% and 0.5% in the subsequent follow-up visits reporting adverse side-effects, mainly gastrointestinal symptoms, as previously reported.[15]

The dietary intervention has been described in detail elsewhere.[4] Briefly, dietary counselling given by a nutritionist aimed to modify dietary intake to conform with dietary recommendations, providing a 55–60 percentage of energy (E%) from carbohydrates,