



# Microbe Mom; A double-blinded randomised controlled trial to assess the ability of *Bifidobacterium breve* 702258 to transfer from mother to infant

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## BACKGROUND

- The composition of the infant microbiome can have a variety of short- and long-term implications for health.
- It has been shown that members of the genus *Bifidobacterium* are dominant colonizers of the infant gut, and low relative abundance of this genus in early life has been associated with an increased risk of non-communicable diseases (Björkstén et al., 2001; Kalliomäki et al., 2008).
- It is unclear if maternal probiotic supplementation in pregnancy can impact the infant gut microbiome.

## RESULTS

- 160 pregnant women with an average age of 33.6 (3.9) years, mean BMI of 24.3 (22.5, 26.5) kg/m<sup>2</sup> and 43% with nulliparity (n=58) were recruited from September 2016 to July 2019.
- Neonatal stool samples were obtained from 135 individual infants (65 in intervention and 70 in control).
- The presence of the supplemented strain was detected through at least two methods (PCR and culture) in two infants in the intervention group (n=2/65, 3.1%) and none in the control group (n=0, 0%), p = 0.230. (Figure 2).

## AIMS

To investigate if maternal supplementation of a formulation of *Bifidobacterium breve* 702258 from early pregnancy until three months postpartum could result in transfer to the infant gut.

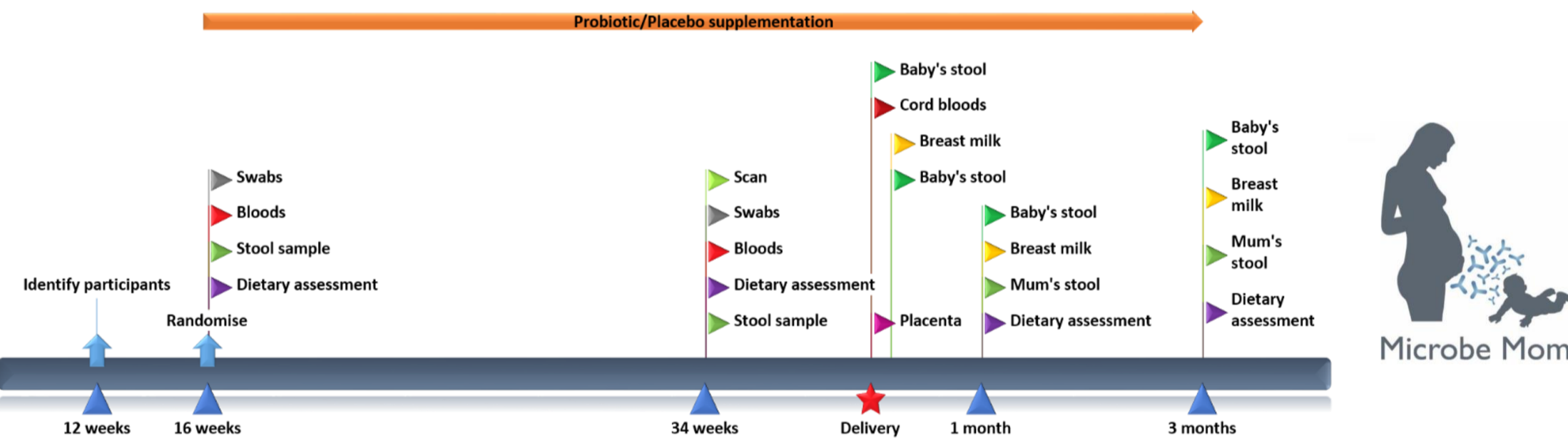


Figure 1 | Randomised controlled trial design and data collection time points

## METHODS

A double-blinded placebo controlled randomised-controlled trial of *B. breve* 702258 (minimum 1x10<sup>9</sup> colony forming units) or placebo taken orally from 16-weeks' gestation until three-months postpartum in healthy pregnant women. (Figure 1.)

Primary outcome was the presence of the supplemented strain in infant stool.

Stool samples were collected from the infants at 1-week, 1-month, or 3-months postpartum, with 120 individual infants' stool samples required to have 80% power to detect a difference in strain transfer between intervention and control.

Presence of the supplemented strain was defined as being detected in the infant stool based on two of three methods, i.e., strain specific PCR, shotgun metagenomic sequencing, or genome sequencing of cultured *B. breve*. Rates of detection were compared using Fisher's exact test

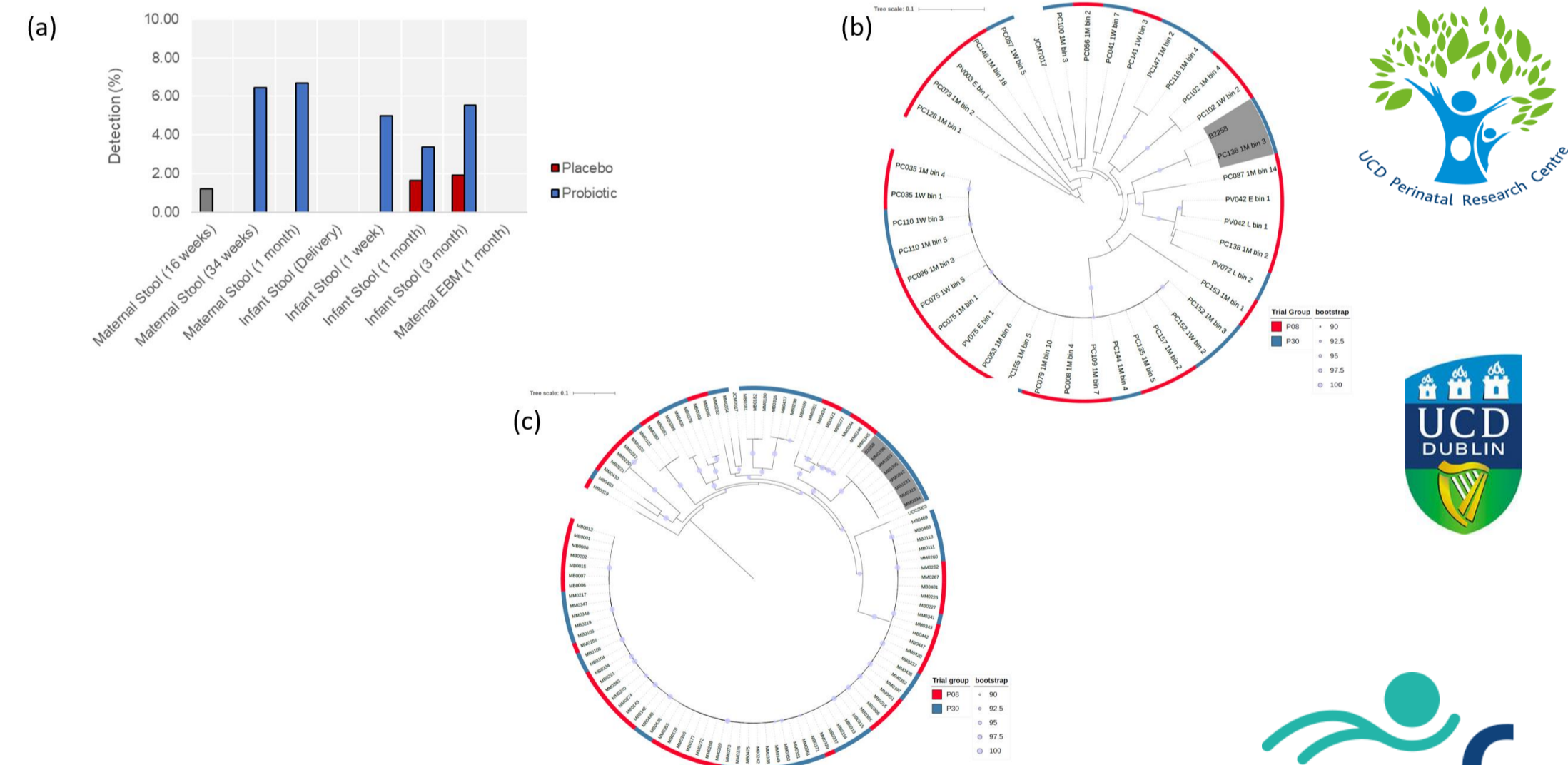


Figure 2 | Detection of supplemented *B. breve* 702258. (a) PCR analysis to detect the strain-specific marker gene of the probiotic strain. Bar charts illustrate the percentage of samples in each trial group that had a positive detection of *B. breve* 702258 for each sample type. (b) Maximum likelihood phylogenetic tree showing the relatedness of metagenome-assembled genomes recovered from the infant stool to the genome of *B. breve* 702258. (c) Phylogenetic tree showing the genomic relatedness of *B. breve* isolates from infant stool to the *B. breve* 702258 genome. Phylogenetic trees were based on the alignment of core SNP regions of all genomes shown.

## Conclusion

Direct strain transfer from mothers to infants of *B. breve* 772058 occurred, albeit infrequently, highlighting potential for maternal supplementation to introduce microbial strains into the infant microbiome.

