

# A theory-based behavioural intervention to reduce formula-milk intake and prevent excessive weight gain during infancy (The Baby Milk Trial): a randomised controlled trial

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## Abstract

**Background** Excessive weight gain during infancy is associated with obesity in later life. We aimed to assess the efficacy of a theory-based behavioural intervention to prevent excessive weight gain in babies fed formula milk.

**Methods** In this single (assessor) blind, parallel group, individually randomised controlled trial conducted in England, we recruited healthy babies who were fed formula milk and their parents within 14 weeks of birth. The behavioural intervention was informed by social cognitive theory and aimed to reduce formula-milk intake, promote responsive feeding, and monitor growth to prevent excessive weight gain ( $\geq 0.67$  SD score [SDS]). The intervention was delivered by trained research nurses to infants up to the age of 6 months through three face-to-face interactions, two telephone contacts, and written materials. The control group received the same number of contacts during which general topics were discussed. The primary outcome was change in weight SDS from birth to 12 months. Analysis was by intention to treat. Ethics approval was given and parents gave written informed consent. This trial is registered with Current Controlled Trials, number ISRCTN20814693.

**Findings** Between March 1, 2011, and June 30, 2015, we randomised 340 babies to the intervention group and 329 to the control group. Retention was 93% ( $n=622$ ) at 6 months and 88% (586) at 12 months; programme engagement was high (94% attended four or five sessions). The intervention reduced milk intake at 3 (by 14%), 4 (12%), 5 (9%), and 6 (7%) months compared with the control group. The intervention slowed weight gain from baseline to 6 months (mean change  $0.32$  SDS vs  $0.42$ ; baseline-adjusted difference between intervention and control  $-0.08$  SDS, 95% CI  $-0.17$  to  $-0.004$ ) but had no effect on weight change from birth to 12 months (baseline-adjusted difference  $-0.04$  SDS,  $-0.17$  to  $0.10$ ). By 12 months, 137 babies in the intervention group (40.3%) and 151 in the control group (45.9%) showed excessive weight gain (odds ratio  $0.84$ , 95% CI  $0.59$  to  $1.17$ ). There were no differences in trial-related safety outcomes between the groups.

**Interpretation** The Baby Milk intervention was acceptable and safe, and it successfully reduced milk intake and weight gain to age 6 months; however, it had no effect on weight gain up to 12 months. Interventions to avoid excessive weight gain in infancy are urgently required but need to be sustained and scalable.

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## Contributors

RL, WH, EW, SJG, and KKO are grant holders; they designed the protocol and contributed to the interpretation of data. SJS conducted the statistical analyses. FW and AS are trial managers. RL wrote the first draft of the abstract. All authors contributed to critical revision of the abstract.

## Declaration of interests

We declare no competing interests.

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