Half of all infants are fed formula milk. However, attrition biases evidence on the long-term safety of formula ingredients. We used unconsented linkage between administrative education and health records of 3,500 young people who were randomised as infants to formula milks, to determine long-term safety and efficacy.

We discuss the steps that were implemented to safeguard the participants’ privacy and achieve ethical and multi-institutional approvals.

Achieving provisional ethical approval took 41 days. Achieving agreement-in-principle to match trial data to individual-level education records took 4 months and 2 weeks, while agreement to match trial data to individual-level hospital records is still underway (5.5 months so far). Delays in institutional approval were largely due to unharmonised data security certificates between the two government departments holding the health and education records. Digitising all handwritten participant identifiers prior to linkage took 9 months. Results on the success of linkage between trial and education records will be presented at the conference.

While directly contributing to the evidence around infant-formula-composition, this project will also act as a proof-of-concept study. Unconsented linkage between dormant RCTs and administrative data could be a novel and cost-effective method to generate evidence on the long-term efficacy and safety of interventions.

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