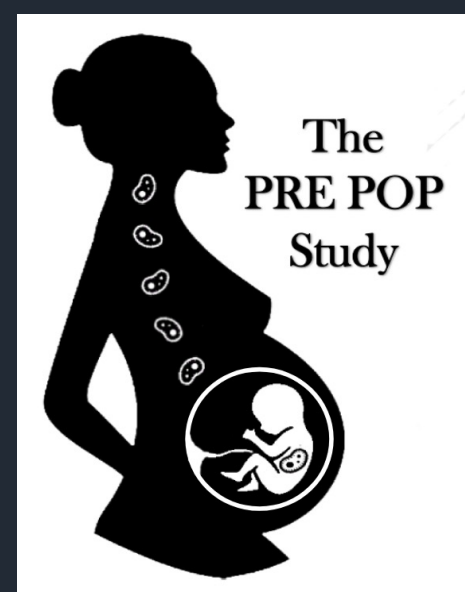
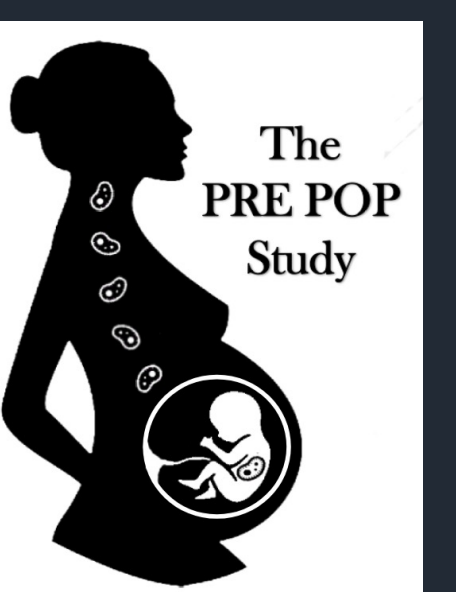




The PrePOP Study



INTRODUCTION

Effective PTB prevention is an urgent unmet clinical need. Vaginal microbial depletion of *Lactobacillus crispatus* is linked to risk of PTB. This trial will investigate the impact of oral probiotic supplementation with *Lactobacillus crispatus* on the maternal microbiome, and its efficacy at PTB prevention in high-risk pregnant populations

STUDY DESIGN

Randomised placebo controlled double blinded trial
Single site - Preterm Birth Service at the National Maternity Hospital, Dublin

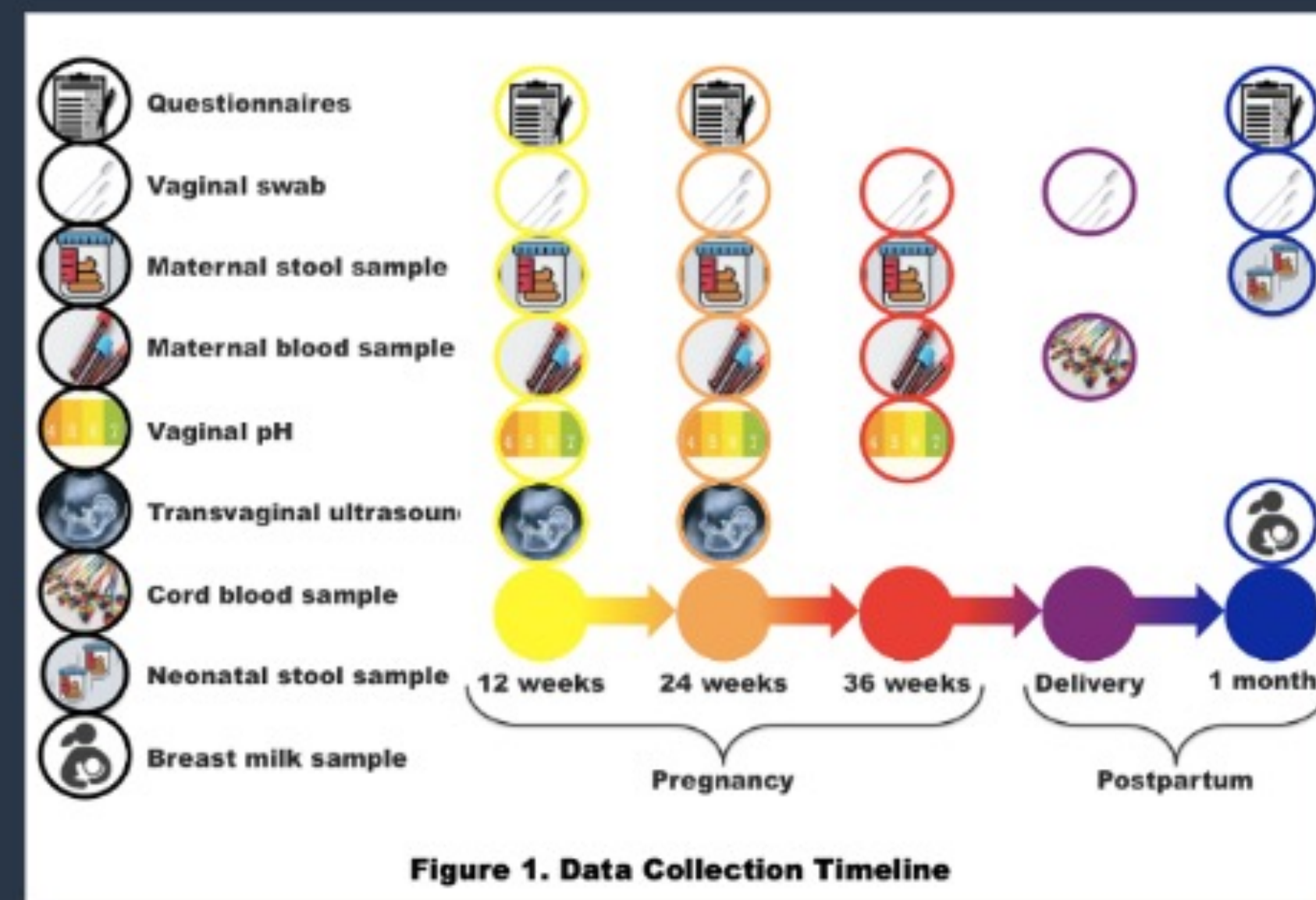


Figure 1. Data Collection Timeline

POPULATION

Pregnancies at high-risk of preterm birth. Women booking at the Preterm Birth service are screened for eligibility Inclusion criteria:

- history of mid-trimester loss or preterm birth prior to 34 weeks,
- cervical procedures including cone biopsy or two previous large-loop-excision-of-transformation-zone
- uterine anomaly.

Exclusion criteria:

- non-english speakers
- women under 18 years of age
- women unable to give informed consent.

INTERVENTION

The intervention is oral supplementation for twelve weeks with probiotic or identical placebo. The probiotic dose will contain:

Lactobacillus crispatus
4x10⁶ colony forming units (CFU)
Lactobacillus rhamnosus
4x10⁶ CFU
Lactobacillus gasseri
0.6x10⁶ CFU
Lactobacillus jensenii
0.4 x10⁶ CFU

Preterm-Birth-Prevention with *Lactobacillus Crispatus* Oral Probiotics:

Protocol for a Double Blinded Randomised Placebo-Controlled Trial

AUTHORS

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INSTITUTIONS

UCD Perinatal Research Centre, Dublin
APC Microbiome, Cork
Imperial College London
University College Dublin

RESULTS & DISCUSSION

150 women will be randomised to power the primary outcome, with 75 in each group.

The primary outcome is relative abundance of *Lactobacillus crispatus* in the vaginal microbiome after twelve weeks of treatment, measured using high-throughput DNA sequencing and/or qPCR. Secondary outcomes will include rate of preterm birth and the abundance of *Lactobacillus crispatus* in the maternal stool, breast milk and neonatal stool after twelve-weeks of supplementation. Cost efficacy analysis will also be performed.



Imperial College
London



This high-quality randomised trial will investigate the therapeutic potential of oral *Lactobacillus crispatus* probiotic in modifying the vaginal microbiome and critically, its potential to reduce the risk of preterm birth.