Individualised PatieNt Care and Treatment FOR MatErnal Diabetes (INFORMED); Intensive Profiling of Dysglycemia in Maternal Diabetes – A Longitudinal Study Protocol

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Objectives: Women with pre-existing diabetes struggle to control glucose levels during pregnancy and are at high risk of pregnancy complications, compared to women without diabetes. Management of postprandial and nocturnal glucose levels are key targets to minimise risk of adverse events during pregnancy. This trial aims to investigate the effect of distinct nutrient patterns on 24-hr glucose levels in pregnant women with pre-existing diabetes to inform future strategies.

Methods: This single-blind randomised controlled trial will recruit 76 pregnant women with pre-existing Type 1 or Type 2 diabetes at ∼10–12 weeks' gestation from the Diabetes in Pregnancy Clinics at Leeds Teaching Hospitals NHS Trust (LTHT). At three timepoints (∼10–12, ∼18–20, and ∼28–34 weeks of gestation), participants will consent to share their medical records (including general health, 7-day continuous glucose data (CGM), and obstetric information), blood and urine samples for metabolite analysis, and complete online questionnaires to assess 3-day diet and general lifestyle. Genetic analysis will also take place. Additionally, a carbohydrate challenge will take place at ∼18–20, and ∼28–34 weeks' gestation while CGM is being measured. Multiple variable analyses and clustering will be used to identify patterns and associations of interest.

Results: Ethical approval has been granted by the Tyne and Wear South Research Ethics Committee (21/NE/0196). The results will be presented at conferences and disseminated in peer-reviewed journals.

Conclusions: Findings of this study will inform the design of a feasibility trial and future interventions. Ultimately, we hope the generated data can be used to support care in women with pre-existing diabetes during pregnancy, and improve maternal and infant outcomes.

Funding Sources: University of Leeds - School of Food Science and Nutrition and Wellcome Trust.