PAIGE2: Pragmatic Lifestyle Pregnancy and Post Pregnancy Intervention for Overweight Women with Gestational Diabetes Mellitus: a Randomised Controlled Clinical Trial
Led by Professor David McCance

Why did we conduct this trial?
Gestational Diabetes Mellitus (GDM) is estimated to affect 1 in 7 pregnancies globally and is compounded by obesity. Outside of pregnancy there is now convincing evidence that lifestyle modification can reduce the incidence of type 2 diabetes by approximately 50% compared with control subjects. In the context of pregnancy however, the problem is the lack of methodologically robust trial evidence for the success of lifestyle interventions in women with previous GDM.

Against this background we designed the PAIGE pilot study to determine the effectiveness of a pragmatic multicomponent postnatal lifestyle intervention among overweight women with a history of GDM. Of note, the results showed a significant reduction in weight, BMI and waist circumference in the intervention compared with the control groups at six months follow up. No one component of the PAIGE pilot was identified as superior to the others, but it was clear that only a pragmatic intervention would have any hope of success and translation into clinical care given the competing demands on these women postnatally. Whether such an intervention could be sustained for 12 months was unknown. Armed with this knowledge, the CHITIN 2017 call was timely as we were keen to explore a definitive Randomised Controlled Trial involving a larger number of people from various cultural backgrounds such as existed in cross-border sites.

What did we do?
This study design involved a 12-month, Randomised Controlled Trial involving women with GDM and body mass index $\geq$25 kg/m^2 recruited during pregnancy. The lifestyle intervention comprised a one-hour virtual educational program at 32-36 weeks gestation. Postpartum, the intervention included monthly phone calls, weekly motivational text messages, weekly step counts (FitBit), and a complementary referral for three months to a Commercial Weight Management Organization (Slimming World). The control arm received usual maternity care. Focus groups were conducted with intervention mothers' post-intervention to determine the acceptability of the study design including utility of a Commercial Weight Management Organization, feasibility of remote patient contact, family involvement and patient satisfaction.

What answer did we get?
124 women (intervention group) and 111 women (control group) were recruited during pregnancy. This decreased to 105 (intervention) and 74 (control) mothers at six weeks postnatal, and to 65 (intervention) and 59 (control) mothers at the end of the study (12 months postnatal). All but six participants in the entire cohort were white. The mean age and BMI of mothers (intervention/control) during pregnancy was 30-31 years old, and 35-36 kg/m^2 respectively. 10 mothers in the intervention group and 15 mothers in the control group smoked while approximately 60% of mothers in each group had had a previous pregnancy. Preliminary results showed a weight reduction in the intervention vs control group (6 weeks to 12 months postnatally) of 2.6 Kg compared with 0.7 Kg (non-significant). At six months follow up, weight loss in the intervention group was 2 kgs compared with 0 kgs in the control group (p=0.08). Of the 41 mothers who attended Slimming World, there was a 3.35% reduction in weight within 12 weeks, corresponding to a 3.55% reduction in BMI. An end-of-study questionnaire, which was completed by 54 women in the intervention group irrespective of whether they had completed the study (excluding withdrawals), highlighted their preference for a mixture of virtual and face-to-face contact within the study. The majority indicated that the Fitbit and counting their steps were the most influential in keeping their motivation during the study. Most women felt they had made significant changes to their lifestyles as a result of participation in the PAIGE2 study.

What should be done now?

The postnatal demands on these women cannot be minimised. Innovative approaches, including the use of virtual technology, were central to the successful completion of PAIGE2, and almost certainly are here to stay. A pragmatic, multicomponent, lifestyle intervention, seems most suited to this subject group, with particular emphasis on text, telephone or an app-based approach, and incorporating goal setting, but attrition rates are high. The high cardiovascular risk of these women needs to be recognised and targeted by NHS prevention strategies informed by data such as the PAIGE2 study. A detailed analysis of the results of PAIGE2 will guide further research.