THE GESTATIONAL DIABETES FUTURE DIABETES PREVENTION STUDY (GODDESS): A FEASIBILITY RANDOMISED CONTROLLED TRIAL AND PROCESS EVALUATION

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Background: Women diagnosed with gestational diabetes mellitus (GDM) are at high risk of developing type 2 diabetes. While lifestyle support could attenuate this risk, there is a lack of preventative interventions for this population.

Aim: The **G**estati**O**nal **D**iab**E**te**S** prevention feasibility **S**tudy (GODDESS) was designed to determine whether a theoretically-based, tailored lifestyle intervention aiming to prevent future diabetes in women with GDM is acceptable and feasible.

Method: A two-arm randomised controlled feasibility trial with process evaluation was conducted in two inner-London hospitals with women with GDM. Participants were randomised to either: lifestyle intervention (four motivational interview-based sessions, a WhatsApp group, a FitBit and electronic resources) during pregnancy until six months postpartum; or usual care. Feasibility and acceptability were measured through routine study data, observations and semi-structured participant interviews, following the Medical Research Council's guidance on process evaluations. Primary preliminary clinical outcome was weight change; secondary clinical outcomes included glycated haemoglobin, diet, physical activity, breastfeeding and depression.

Result: 50 women were randomised, 26 to the intervention and 24 to the control group. After adjusting for patient preference, 34 were allocated to intervention and 16 to control group. Mean weight change was -2.1kg (±9.0) in the intervention group and +4.4kg (±4.9) in the control group (p=0.036 unadjusted, p=0.057 unadjusted). Nearly half (46.2%, n=6) of those in the intervention group who completed the study lost 5% or more of their body weight compared to one participant in the control group (p=0.07). It was feasible to recruit women within the planned timeframe. Attrition was high, with various life events, lack of time and COVID-19 cited as constraints. The intervention was acceptable to participants, who cited improved emotional wellbeing, eating behaviour and understanding of their relationship with food, and decreased feelings of stigma and isolation as impacts.

Conclusion: The GODDESS study was feasible and acceptable, but attrition in the six months postpartum needs to be addressed. The findings suggest that the intervention may result in weight loss. Optimisation of the intervention and methods is an important next step.