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SUMMARY

Prevention programmes targeting the worldwide public health problem of obesity are needed. Especially in pregnancy, because maternal obesity puts women at risk for the development of several complications or adverse health outcomes, including gestational diabetes mellitus (GDM). GDM is defined as a carbohydrate intolerance resulting in hyperglycaemia of variable severity with onset or first recognition during pregnancy. Several adverse health outcomes for both mother and child are associated with GDM, such as a higher birthweight and increased risk for caesarean section. Additionally, women with a history of GDM have an even larger risk of developing GDM in a subsequent pregnancy. On the long term, GDM is a precursor for the development of type 2 diabetes mellitus for both mother and child. Therefore, specific GDM prevention programmes for overweight and obese women are important. Prevention programmes based on theoretical frameworks and aiming for a prevention of excessive gestational weight gain (GWG), by targeting physical activity and diet behaviours in pregnancy have the potential to reduce the development of GDM (**Chapter 1**).

This thesis describes the development and evaluation of the DALI lifestyle intervention programme for GDM prevention among overweight and obese pregnant women across nine European countries. DALI is an acronym for vitamin **D** And Lifestyle Intervention for GDM prevention.

Exploration of beliefs, barriers and preferences to adopt a healthy lifestyle

In the first section of this thesis, the target population is consulted to understand the beliefs, barriers and preferences of overweight and obese pregnant women regarding lifestyle changes and lifestyle programmes that could assist in making these changes. The involvement of the target population is key for developing effective lifestyle intervention programmes. Up until now research among European overweight and obese women was scarce. **Chapter 2** described the study in which we gathered information from overweight and obese pregnant women across nine European countries. Our findings indicated that pregnancy is a key time for lifestyle interventions. The health of their unborn child is an important motivating factor to live healthily. Furthermore, women appear highly receptive to health information and advice, especially about their increased personal risk caused by their weight. Barriers regarding physical activity and diet experienced by overweight first-time mothers and multipara women appear to be different, which is a factor that should be considered during counselling. For women to consider attending a lifestyle programme flexibility in attendance time and place is thought to be important. In designing lifestyle intervention programmes, the previous points should be considered. Furthermore, health care professionals should use the opportunity of pregnancy to provide information on risks, lifestyle modification and weight management.

Design of the DALI study

The DALI study, a multicentre randomised controlled trial (RCT), was designed to collate evidence about the epidemiology of GDM in Europe, to promote pan-European standards and measures for GDM and to identify suitable preventive measures against GDM. The background and methods of the DALI study are presented in **chapter 3**. The developed DALI intervention was based on the needs and preferences gathered of the target population described in **chapter 2**. The DALI intervention consisted of a 2x2 vitamin D arm and a 2x2 lifestyle arm. In the 2x2 vitamin D arm women received supplementation of either 1600IU/day vitamin D or placebo with or without a lifestyle intervention targeting physical activity and healthy eating. In the 2x2 lifestyle arm women were randomised into a lifestyle intervention targeting physical activity (PA), healthy eating (HE), a combination of healthy eating and physical activity (HE+PA) or into the control group (UC: usual care). The lifestyle intervention consisted of five face-to-face sessions of approximately 30-45 minutes with a lifestyle coach trained in motivational interviewing (MI). Participant had the option of four additional telephone calls in between sessions. The sessions employed information on GDM, weight management, seven healthy eating messages and five physical activity messages aimed to improve lifestyle behaviour. Tools to assist in making lifestyle changes, such as a pedometer, dynaband or dietary record, were provided. Data was collected on both the mother and her child before 20 weeks of gestation, at 24-28 weeks of gestation, at 35-37 weeks of gestation and after delivery. The primary outcomes were maternal GWG, fasting glucose and insulin sensitivity.

Effect evaluation of DALI lifestyle pilot

In the second section of this thesis, after the development of the intervention, a pilot study was performed. As described in **chapter 4** [300], the main aim of the pilot study was to test the procedures, methodology and lifestyle interventions for the forthcoming full RCT. This pilot lifestyle intervention compared the impact of three lifestyle interventions (HE; PA; HE+PA) on GDM risk. Our primary outcomes were GWG, fasting glucose and insulin sensitivity. A large proportion of the women (22%) had GDM in the beginning of pregnancy and was not included. Among the total of 150 participants 32% developed GDM by 35-37 weeks and 20% of the women achieved a GWG below 5 kg. Only the HE intervention was associated with 1.6 kg less GWG and 0.3 mmol/L lower fasting glucose compared to the PA intervention at the end of pregnancy. No significant differences were observed between the HE+PA and the other two groups. The results of this pilot intervention are in favour of a HE intervention in overweight and obese women, although a larger trial reproducing these results is clearly needed.

Process evaluation DALI lifestyle pilot

It is important to evaluate process variables to indicate how a planned intervention was conducted and to provide insight into why an intervention has shown positive or negative results. Therefore, in **chapter 5** we aimed to assess reach, dose delivered, fidelity and

satisfaction and investigated whether these process elements could explain differential effects of the intervention on changes in the primary outcome GWG. The results indicated that one-third of the invited women were willing to participate, which was a similar response rate in comparison to other intervention studies. The intervention was delivered satisfactorily (8.6 on a 10 point scale) with 63% of the women receiving all intervention session. The overall fidelity scores of the intervention delivery did not achieve expert MI standards, although high variance of MI competence was observed between practitioners. Furthermore, no association with GWG was found for implementation of MI by the lifestyle coaches or the degree of participation of the participants. It was concluded that the DALI intervention was well received across a range of European countries and may even be feasible to implement more widely across Europe.

Effect evaluation of physical activity and diet in the DALI lifestyle trial

In **chapter 6** the effectiveness of the DALI lifestyle intervention on objectively measured physical activity and diet is presented and subsequently it is examined how these changes were related to the primary outcomes GWG, fasting glucose and insulin sensitivity. For physical activity an effect on counts per minutes was found in the PA group mid-pregnancy and for diet an effect on overall dietary scores in the HE+PA and HE group mid-pregnancy. The intervention did not seem to have a mediating effect through physical activity and dietary changes on GWG and glucose metabolism. However, the small sample size could have led to not finding a mediation effect that is actually present (type 2 error). Furthermore, it is possible that ‘small changes’ in physical activity and diet are too small to be detected but do result in long-term changes on (gestational) weight gain. Further research needs to investigate other possible biopsychological or environmental factors that could play a more prominent role in total GWG and glucose metabolism during pregnancy.

Fidelity

Treatment fidelity refers to the methodological strategies used to monitor and enhance the reliability and validity of behavioural interventions. It is known that treatment fidelity in MI has predictive validity of the effect of the intervention. However, as many research trials fail to assess treatment fidelity it is impossible to distinguish between high- and low-quality MI interventions. **Chapter 7** [158] discusses the collecting, selecting, coding and reporting of MI treatment fidelity in RCTs. Practical recommendations regarding the preferred MI fidelity instrument, the amount of coded audio samples, the training of coders and the reporting of the results are provided. To facilitate high quality of future studies and comparison among trials it is important that researchers would take notion of the provided recommendations.

General discussion

In the final chapter (**chapter 8**) the main findings of this thesis are put in broader perspective, methodologic considerations are discussed and a reflection on chapter 2 to 7 is provided. Additionally, implications and recommendations for clinical practice and further research are given. Overall, the moderately intense physical activity and healthy eating lifestyle intervention could impact on GWG of overweight and obese pregnant women. However, a lower incidence for GDM was not found. These results are in line with other recently conducted research projects. If the DALI intervention is implemented in usual practice it is important to provide sufficient training and supervision of the lifestyle coaches to maintain the level of MI counselling. Furthermore, it might be considered in future research to extend the lifestyle counselling session to the postpartum period and to include all overweight women (BMI ≥ 25). It is important that we aim to disrupt in as many ways as possible the mother-offspring vicious 'obesogenic' cycle.