Lifestyle Counselling Intervention to prevent Gestational Diabetes Mellitus

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CHAPTER 1:

General introduction

OBESITY

Obesity is a worldwide public health problem. It is characterized by an abnormal or excessive amount of body fat. Body mass index (BMI) is a commonly used measure for adiposity. The World Health Organization (WHO) and Institute of Medicine (IOM) defined a BMI of 25 to 29.9 kg/m^2 as overweight and a BMI of 30 or more as obese [350]. Worldwide about 39% of adults aged ≥18 years were overweight in 2014 (about 1.9 billion people), furthermore 13% were even considered obese (about 600 million people) [349]. In Europe these estimates are even higher, based on data of 2008 over 50% of both men and women were overweight, and roughly 23% women and 20% men were considered obese [347]. Excessive weight imposes additional risks for a number of diseases, such as diabetes, cardiovascular diseases and cancer [173]. Obesity is difficult to treat, therefore prevention is critical.

OBESITY IN PREGNANCY

Obesity influences reproductive health and affects chances of becoming pregnant [73]. Maternal obesity puts women who become pregnant at increased risk of several complications during pregnancy and childbirth, including gestational diabetes mellitus (GDM), hypertension, preeclampsia, depression, instrumental or caesarean delivery and surgical site infection [195]. Furthermore, babies from overweight and obese women have a greater risk of preterm delivery, fetal defects, congenital anomalies, perinatal death and being born large-for-gestational age [195]. Obesity of the mother has profound effects on the future health of the offspring [244], such as a lifelong risk of obesity, which has the potential to result in a transgenerational vicious cycle of obesity [46].

GESTATIONAL DIABETES MELLITUS

GDM is defined as *"carbohydrate intolerance resulting in hyperglycaemia of variable severity with onset or first recognition during pregnancy" [346]* .

In pregnancy, insulin resistance increases physiologically in order to ensure nutrient supply for the fetus. Normally, this increased insulin resistance is overcome by an increase in insulin secretion. However when pancreatic beta cell function is insufficient to meet the body's insulin needs, GDM develops. The International Association of Diabetes in Pregnancy Study Group (IADPSG) developed cut points for GDM diagnosis, which are recently adopted by WHO. GDM is diagnosed if women on a 75 gram oral glucose tolerance test have a fasting venous plasma glucose ≥ 5.1 mmol/L and/or 1 hour glucose ≥10 mmol/L and/or 2 hour glucose ≥ 8.5 mmol/L [209,348].

In Europe between 2 and 6% of pregnancies were estimated to be affected by GDM in 2012 [39], although at that time lack of consensus on testing methods and threshold values hampered comparison. The IADPSG/WHO thresholds resulted in increased GDM prevalence rates compared to the old cut points (e.g. in a Nordic Caucasian population prevalence increased from 6.1 to 7.4%) [140].

Obese pregnant women are at higher risk (reported odds ratio of 3.0 and higher) to develop GDM compared to normal weight women, whereby the risk increases further for every increase of 1 kg/m^2 in BMI [60,327]. Furthermore, multiple risk factors increase the overall risk even more, such as: history of impaired glucose tolerance or GDM; certain ethnic groups (Hispanic-American, African-American, Native-American, South or East Asian, Pacific Islander); family history of diabetes; maternal age above 25 years; previous delivery of baby with birth weight above 4 kg; previous unexplained perinatal loss or birth of a malformed child; maternal birth weight above 4 kg or below 2.7 kg; glycosuria at first prenatal visit; medical condition associated with development of diabetes (such as metabolic syndrome, polycystic ovary syndrome, current use of glucocorticoids, hypertension) [68]. Moreover, excessive gestational weight gain (GWG) increases the risk of GDM by a factor of 1.4, although it is unclear if effect modification of maternal BMI categories is present [38].

Several adverse outcomes for both the mother and the child have been associated with GDM, such as being born large-for-gestational age, primary caesarean delivery, higher cord-blood serum C-peptide and neonatal hypoglycaemia [210]. On the long term, women with a history of GDM have a sevenfold increased risk to develop type 2 diabetes [22]. Both obesity and GDM have an independent effect on adverse pregnancy outcomes, but combined they have a greater impact than either one alone [47]. Therefore especially in an obese population prevention of GDM and follow up care after a GDM pregnancy is essential.

GESTATIONAL WEIGHT GAIN

During pregnancy maternal weight gain is a summation of the weight of the fetus, uterus, placenta, blood, amniotic and extracellular fluid, and increased maternal fat and lean mass [258]. The IOM developed recommendations for a healthy weight gain during pregnancy for different BMI categories. The recommended range for gestational weight gain (GWG) is 5-9 kilo for obese women to minimize risks and complications related to obesity in pregnancy, compared to a GWG of 11.5-16 kilo for normal weight women [155].

Excessive GWG could affect the growth of the unborn child and lead to large-for-gestational age babies [296]. These babies are at higher risk of being overweight at a later age themselves [238,325], which could be due to their birth weight [185], but also to genetic factors and lifestyle habits, such as high caloric food intake and low levels of physical activity [157,310]. A consequence of excessive GWG for the mother is the retention of weight after pregnancy and

as a result of the additional weight she will start each subsequent pregnancy more obese. Interventions to avoid excessive weight gain are needed [238].

LIFESTYLE

Excessive GWG is mostly a consequence of an imbalance between energy intake and energy expenditure. Accurate maternal dietary intake [154] could help prevent detrimental effects to fetal growth and birth outcomes [5]. A healthy diet containing sufficient fresh vegetables, fruit, legumes, nuts, whole grains and fish, but avoidance of red and processed meat, refined grain products, eggs and high-fat dairy could be beneficial in the prevention of GDM [289].

Furthermore, obese women should be encouraged to incorporate 30 minutes of at least moderate physical activity a day, unless there are medical or obstetric contra-indications [15]. Regular physical activity could improve cardiovascular condition, glucose tolerance, increase muscle mass and bone density [6]. Furthermore, active pregnant women have reduced rates of nausea and vomiting, and experienced less lower back pain [104].

Research has shown that guidance on diet and physical activity throughout pregnancy from a dietician or health professional is appreciated by pregnant women, especially since women indicated that information regarding diet, physical activity and GWG is currently lacking [92,341]. Lifestyle interventions implemented in addition to usual care during pregnancy have shown to improve maternal diet and physical activity patterns of obese pregnant women [85]. In the prevention of excessive GWG behaviour modification techniques such as self-monitoring and goal setting, combined with frequent contact, individual attention and professional involvement appeared most effective [302].

The conducted reviews and meta-analyses seem not to support one superior strategy with regard to GDM prevention. In one review physical activity is shown beneficial in the prevention of GDM (28% lower risk of GDM compared to a control condition) [285], while in another recent review study no clear beneficial effect on GDM of a combined physical activity and diet intervention was found, although regarding GWG the women in the exercise and diet intervention gained 0.76 kg less compared to the women in the control group [17]. In contrast, it was shown previously that a dietary alone intervention was most effective in reducing GWG compared to a combined or physical activity alone intervention [319]. The opposite effects or lack of effect on GDM found in the studies conducted so far might have been due to low statistical power, poor adherence to the study intervention and/or to the fact that lifestyle interventions may not be able to overcome the pregnancy induced insulin resistance [126].

More translational research into lifestyle intervention programmes for overweight and obese women is clearly warranted [285] and indeed underway [17]. A clear knowledge gap seems to exist on the most effective lifestyle intervention during pregnancy: healthy eating intervention, physical activity intervention, or a combined healthy eating and physical activity intervention.

CHANGING HEALTH BEHAVIOUR: THEORY

Application of theoretical frameworks enhance the evidence for effective behavioural change interventions [70]. Theory based research allows according to Nigg et al. (2008) for; (1) an understanding of the involved mechanisms; (2) an understanding of the failure and success factors; (3) an understanding of the factors influencing the short and long term effects; (4) an identification of possible mediating factors; and (5) a determination why the intervention was successful [241]. Determinants of behaviour change differ across populations, among individuals and could even change over time [36].

Two highly recommended frameworks are the health action process approach (HAPA) model and the self-determination theory (SDT), HAPA helps to answer the "how to?" question and SDT the "how come?" or "why?" questions [239]. Furthermore, Motivational Interviewing (MI) shares the same values as SDT [197], therefore SDT is frequently seen as the 'theory of MI' and MI as the 'intervention method of SDT' [316].

Health action process approach

HAPA is a model of health behaviour change, informed by social cognitive theory and supported by empirical evidence. This framework suggests that adopting (pre-intenders), initiating (intenders) and maintaining (actors) behaviour change is a structured process including a motivational and volitional phase [293], see Figure 1.1. The motivational phase covers the process of intention formation that is determined by three variables (a) risk perception; (b) outcome expectancies; and (c) perceived task self-efficacy, or the person's belief in her capability to complete the task and reach her goals [18]. The intention-behaviour gap is bridged by action planning and coping planning, transitioning into the volitional phase, where again self-efficacy (maintenance, recovery) plays a crucial role in maintaining behaviour change.

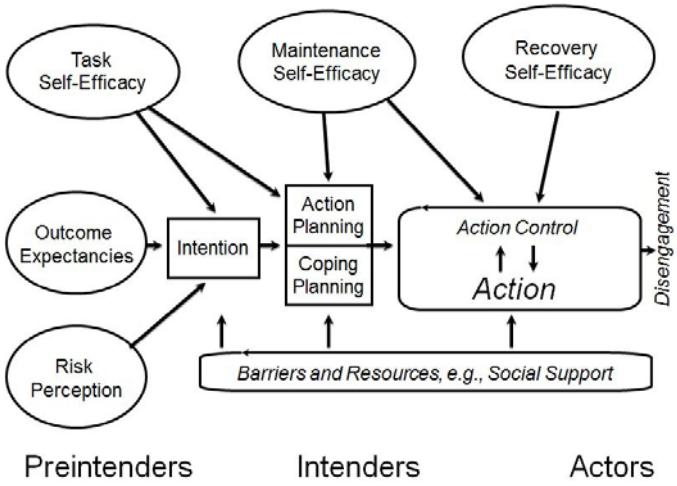

Figure 1.1: The health action process approach derived from Schwarzer (2008) [293]
(source: http://userpage.fu-berlin.de/health/hapa.htm)

Self-determination theory

SDT is a theoretical framework of human motivation and behaviour developed by Deci and Ryan [79,80]. This theoretical framework is based on the assumption that people have three basic psychological needs: competence, relatedness and autonomy. Competence refers to the desire to master the environment. Relatedness deals with the desire to interact with other people. Autonomy means having a free choice of doing something and acting out of own interest and values. It is suggested that when people experience these three basic needs, they become intrinsically motivated.

SDT distinguishes on a continuum among various types of motivation [80], (a) amotivation, or the absence of intention, motivation and self-determination; (b) extrinsic motivation – external regulation, the motivation which is regulated by external motivation and incentives; (c) extrinsic motivation – introjected regulation, the motivation is a consequence of self-worth, treats of guilt or shame; (d) extrinsic motivation – identified regulation, the motivation becomes part of their identity and is worthwhile; for example a reason for changing one's behaviour could be for one's health or well-being; (e) extrinsic motivation - integrated regulation, the motivation is fully integrated with other aspects of one's self; and (f) intrinsic motivation, which is driven by interest or enjoyment in the task itself. SDT highlighted that having an autonomous style of self-regulation (identified, integrated and intrinsic) leads to more positive behavioural outcomes, for which evidence is found in exercise behaviour [315], eating behaviour [333] and weight control [317]. Figure 1.2 shows a visual presentation of the motivational continuum. It is described as quite exclusive forms of motivation, although it is common that these motivations and regulations coexist for the same behaviour, could change over time or differ in different contexts [251]. For example, a pregnant women may value exercise and healthy eating because she values her own health (identified regulation), on the other hand she may have feelings of guilt for her unborn child if she does not exercise and eat healthy while pregnant (introjected regulation). The dynamics of motivation are key to long term success [286].

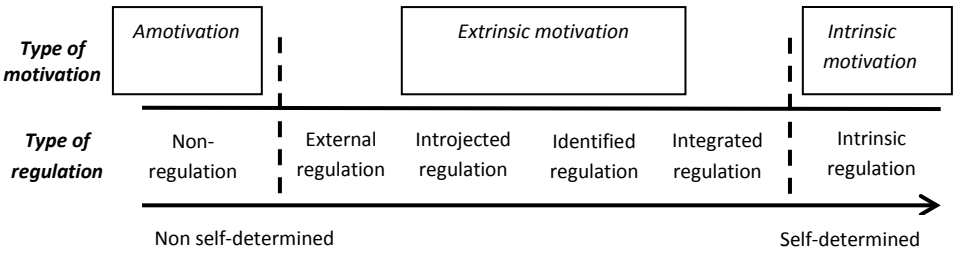

Figure 1.2: Continuum of motivation according the self-determination theory (adapted from: [80])

Motivational interviewing

"Motivational interviewing (MI) is defined as: a collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion" [216,217]

MI is widely adopted as a tool for facilitating change and is shown effective or equally effective to other interventions across many behaviours [41,143,187,188,282]. MI is designed so that practitioners assist clients in talking themselves into change [217]. The five main principles of MI are: (1) express empathy; (2) develop discrepancy; (3) avoid argumentation; (4) roll with resistance; and (5) support self-efficacy. Strategies to acquire these principles are: asking open-ended questions; making reflections on what the participant has said; showing empathy; making confirmations; and accepting the participant's own choice [215].

Contrary to other counselling methods, MI is a fluid intervention whereby its users ensure its quality [26]. To protect the dissemination of MI the founders, Miller and Rollnick, wrote three MI books [215-217], and research articles to explain MI [212], what MI is [277] and is not [218], so the original identity of MI would not be lost, while its method spread around the world. Furthermore, they organised courses to become MI trainers and developed a coding system (Motivational Interviewing Skill Code (MISC) [116]) for measuring fidelity of MI. The fact that no license code or certification was needed to practice MI led to a world-wide use of MI and open sharing of its materials and methods [26], which started in alcohol probation but soon spread to other areas, such as health behaviour (smoking cessation, physical activity, diet). The trained MI trainers across the world organised a MI Network of trainers (MINT-network: motivationalinterviewing.org) which hold annual meetings to share experiences and knowledge across the field and together try to keep the original spirit of MI a life.

Professionals experienced MI as a useful method to deal with difficult situations, such as working with obese pregnant women [33]. In contrast to other change strategies (e.g. education, persuasion, scare tactics), MI motivates change from within the participant.

THE DALI PROJECT

In 2010, the prevention project called "DALI" started, to fulfil the call from policy makers to develop standardised well designed randomised trials to identify suitable preventive measures against GDM [247,319]. DALI is an acronym for vitamin **D A**nd **L**ifestyle **I**ntervention for GDM prevention. In this research project the aim is to investigate the effectiveness of a lifestyle counselling approach and a vitamin D approach in the antenatal period compared to a control/placebo group in the prevention of GDM. Furthermore, this project is designed to collate evidence about the epidemiology of GDM in Europe and to promote pan-European standards and measures for GDM. This is important, because currently no generally accepted

and uniform European agreement on screening approaches and diagnostic standards for GDM exist [39]. DALI is an European project of 13 partners (www.dali-project.eu). In nine European countries (Austria, Belgium, Denmark, Ireland, Italy, Poland, Spain, The Netherlands, and United Kingdom) overweight and obese pregnant women were recruited. The focus of DALI is on a population of increased risk of developing GDM [60,327].

AIM OF THIS THESIS

Before complex interventions can be implemented in practice they should follow a developing, piloting and evaluating phase [70]. In this thesis only a part of the conducted research within the DALI project is described with its main focus regarding the lifestyle intervention. The aim of this thesis was to develop and evaluate a lifestyle intervention for GDM prevention among overweight and obese pregnant women across Europe.

OUTLINE OF THIS THESIS

Chapter 2 presents results from (structured) interviews across nine European countries. These interviews were conducted to investigate beliefs, barriers and preferences of pregnant overweight and obese women regarding prevention of GDM.

Based on the data gathered in these interviews and guided by the HAPA model and MI a lifestyle counselling intervention programme for the prevention of GDM was developed. The intervention and is materials were translated in a total of seven different languages (from English into Danish, Dutch, German, Italian, Spanish/Catalan, Polish). The design of this intervention programme along with all evaluation methods is described in **chapter 3.**

Chapter 4 reports the primary outcomes of the pilot study (GWG, fasting glucose and Homeostasis Model Assessment – insulin resistance (HOMA-IR)). This chapter is followed by a process evaluation of the pilot study in **chapter 5** in which process elements are described and related to the primary outcome GWG.

After piloting the DALI study a randomised controlled trial (RCT) is conducted. In **chapter 6** the results of the physical activity and dietary data measured with objective accelerometer and dietary record data are evaluated. Furthermore, in this chapter it is examined how these results mediate GWG, fasting glucose and HOMA-IR.

Chapter 7 describes recommendations for future researchers to measure fidelity of MI in randomised trials.

The general discussion (**chapter 8**) presents an overview of the main findings and critically discusses the theoretical, practical and methodological issues encountered in this thesis. Furthermore, it provides suggestions for practice and future research.