Lifestyle Counselling Intervention to prevent Gestational Diabetes Mellitus

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CHAPTER 8:

General discussion

This thesis described the vitamin D and Lifestyle Study (DALI): a large European randomised (controlled) trial carried out with pregnant overweight and obese women. Several aspects of the study, with the main focus to improve lifestyle related behaviour and to prevent the development of gestational diabetes mellitus (GDM) were reported. In this final chapter the main findings of this thesis are reformulated and put in broader perspective, followed by an elaboration on methodological considerations and a reflection of the findings. In the end, potential implications for clinical practice and further research are provided.

MAIN FINDINGS

The main objective of this thesis was *to develop and evaluate a lifestyle intervention to prevent the development of GDM in overweight and obese pregnant women across Europe.* The research described in this thesis is part of a large European collaboration with 13 partners. This thesis described only a small part of all data collected and focused foremost on the data collected in the lifestyle pilot.

To explore beliefs, barriers and preferences among our target population, in **chapter 2** [159] qualitative interviews and questionnaire data from nine European countries were gathered. We found that overweight and obese pregnant women valued information on their additional personal risk caused by their obesity. We also found that an individually tailored counselling intervention was appreciated by these women and that it was especially important to consider the different barriers experienced by first-time and multipara mothers. Based on chapter 2 [159] a lifestyle intervention was developed as described in **chapter 3** [160]**.** A randomised controlled trial (RCT) targeting pregnant women with a body mass index (BMI) of 29 or higher in Austria, Belgium, Denmark, Ireland, Italy, the Netherlands, Poland, Spain and the UK. The RCT consisted of a lifestyle and a vitamin D 2x2 factorial design. In the lifestyle 2x2 design was usual care (control) compared to physical activity (PA) or healthy eating (HE) or healthy eating and physical activity (HE+PA) lifestyle intervention. The intervention programme consisted of five individual face-to-face sessions and four optional telephone session delivered by a lifestyle coach trained in the principles of motivational interviewing (MI). The face-to-face sessions included a discussion about the risks of GDM, a weight gain target of less than 5 kg and either seven healthy eating 'messages' and/or five physical activity 'messages' depending on randomisation. In the vitamin D 2x2 design women were randomised to either a vitamin D group, which received daily 1600 IU vitamin D supplementation, a placebo group or a vitamin D with additional counselling on HE+PA, or a placebo with additional counselling on HE+PA. The HE+PA intervention was identical to the intervention delivered in the lifestyle 2x2.

First a pilot study was conducted. As described in **chapter 4** [300], the HE intervention showed positive effects on gestational weight gain (GWG) and fasting glucose compared to the women in the PA group. These results found in the pilot DALI lifestyle study needed to be replicated in a larger trial for confirmation in which a control group is added. In **chapter 5** the process

evaluation of the pilot DALI lifestyle study was reported. It became clear that the intervention was well delivered and received by the study population. Even though, this was a pragmatic trial and the performance of most of the practitioners in this study left room for improvement, some practitioners did obtain certain principles of MI. An indication existed that the more skilled MI practitioners were better able to minimize GWG in the PA group compared to the lesser skilled MI practitioners.

The results of the pilot lifestyle study **(chapter 4** [300] **and 5)** informed a larger lifestyle trial study in 436 women. No major changes were made to the protocol, besides given more prominence to a clearer target of a maximum GWG of 5 kilo and more emphasis on the 'reduce carbohydrates' message. Furthermore, the final face-to-face session was scheduled closer to the measurement at 35 weeks of gestation. The lifestyle trial had a RCT design, including three lifestyle interventions (similar to the pilot lifestyle study) and a control arm (usual care). The primary effects (not part of this thesis) of the DALI lifestyle trial showed an reduction of 2 kilo GWG of the HE+PA group compared to the control condition, although no effect was found on metabolic parameters or in the prevention of GDM [299]. In **chapter 6** it was shown that the dietary quality index (DQI) was improved in mid-pregnancy for the women in the HE and HE+PA groups and that the women in the PA group improved their counts per minute (raw accelerometer output) in mid-pregnancy. However, the DQI and total physical activity did not indirectly have a mediation effect on GWG, fasting glucose or insulin sensitivity in any of the intervention groups.

In the evaluation of RCT's it is valuable to distinguish between high and low quality studies. However, in RCTs conducted so far with MI as intervention method a correct assessment of treatment fidelity is mostly lacking. Therefore, in **chapter 7** [158], we stress the importance of measuring MI fidelity in RCTs and provide researchers with practical recommendations for the collection, selection, coding and reporting of MI fidelity data.

COMPARISON TO OTHER STUDIES

Prevention of gestational diabetes mellitus

In the same time period as the DALI intervention other intervention studies were conducted among overweight and obese pregnant women, since high methodological sound studies in this study population were needed to advise policy makers on the best approach in order to prevent the development of GDM [247,319]. Two major studies, LIMIT and UPBEAT (UK Pregnancies Better Eating and Activity Trial), used a combined healthy eating and physical activity intervention. The UPBEAT study randomised about 1500 obese pregnant women into an intervention that consisted of one face-to-face session with a health trainer followed by eight consecutive weekly group sessions with advice regarding diet and physical activity [262]. In the LIMIT study participants received lifestyle advice during two face-to-face sessions with a dietician and four sessions with a research assistant [87]. Both studies were ineffective in the

prevention of GDM [86,261]. On the contrary, in the smaller RADIEL study conducted in Finland (n=269 women), in which women attended a group session with a dietician in the beginning of pregnancy followed by three individual counselling sessions on diet, physical activity and weight control, a reduction of GDM risk by 39% was found in obese women or in women with a history of GDM [171].

Changes in gestational weight gain

Excessive GWG is thought to be a precursor of GDM as higher GWG lead to greater maternal body fat and subsequently insulin resistance [137]. In the UPBEAT trial the women in de intervention group gained 0.5 kilo less weight compared to the control condition, although both groups gained within the limits of recommended GWG [261]. Both the RADIEL and the LIMIT study did not find a significant difference in GWG in third trimester between the intervention and control group [86,171].

Ongoing studies

Some studies are still ongoing in Europe to test lifestyle interventions among overweight and obese pregnant women. In the UK the HELP (Healthy Eating and Lifestyle in Pregnancy) trial cluster randomises 20 maternity units, in which a total of 570 obese pregnant women will either receive a 1.5 hour weekly weight management group intervention until 6 weeks postpartum in order to reduce BMI at 12 months postpartum or usual care [162]. In the south-east of Germany the GeliS trial (acronym for “Gesund leben in der Schwangerschaft”) randomises 2500 pregnant women with a BMI between 18.5 and 40 into a lifestyle intervention programme with three face-to-face sessions during pregnancy and one session post-partum emphasizing diet, physical activity and weight management or to a control group receiving usual care. The primary goal of this intervention is to decrease the proportion of women with excessive GWG [268].

In other parts of the world research among this target group is also ongoing. In Australia 370 overweight and obese women receive a weekly intervention of 5 minute phone calls based on MI and email/text contacts from first trimester until birth, with the intention to reduce the incidence of GDM, as well as secondary outcomes such as reduce GWG, reduce incidence of large for gestational age, improve OGTT results and improve self-efficacy/psychological well-being [237]. In the United States a consortium between seven clinical centres called Lifestyle Interventions for expecting Moms (LIFE-Moms) is ongoing, with the main aim to identify effective lifestyle interventions that are able to improve GWG, glycaemic control and pregnancy related outcomes among overweight and obese pregnant women. Each clinical centre conducts its own trial, but all behavioural and lifestyle interventions collect core measures consistently [3].

Currently, an international world-wide collaboration (International Weight Management in Pregnancy: i-WIP) is pooling data from previously conducted RCTs and is looking into the effect on GWG and composite adverse maternal and fetal outcomes [284]. Pooling data increases the numbers involved and would generate stronger conclusions. This is also warranted for studies preventing GDM, but limited by the different cut points and testing methods used among several studies.

METHODOLOGICAL CONSIDERATIONS AND REFLECTIONS

RCTs are considered highest in the hierarchy of research designs for evaluating the effectiveness of interventions [67]. As the reporting of RCTs was not always optimal the CONSORT group (Consolidated Standards of Reporting Trials) developed a statement to improve the quality of reporting of RCTs [290]. In the next section the methodological considerations in light of the CONSORT statement are described and reflections on the DALI research are given.

Recruitment

The DALI study was initially designed to follow a 2x2x2 randomised design, in which recruitment for the vitamin D trial and the lifestyle trial occurred simultaneously. However, due to a delay in medical ethical approval for the vitamin D trial in certain countries it was decided to split both trials and first continue with the recruitment for the lifestyle trial. In certain countries, especially with a more profound obesity epidemic (e.g. UK) recruitment was fairly easy compared to other countries with a lower rate of obesity (e.g. the Netherlands) [351]. Furthermore, in some countries an unexpected high exclusion rate due to impaired glucose intolerance at baseline measurement made it a challenge to include enough women into the study (e.g. Denmark). In the end, the decision (to start with recruitment for the lifestyle trial) led to an appropriate power for the lifestyle trial, but for an underpowered vitamin D trial. Consequently, not all countries were equally represented in the vitamin D trial.

The involvement of nine European countries, with its different health systems and different cultures, made this study a challenge. The main difference in maternal health care organisation between the Netherlands (the country in which we were responsible for recruitment) and the other countries is that in the other countries women directly attend a hospital for her maternity care. Primary care in the Netherlands involves midwives and GP's (the latter in only 0.5% of all births), and only for secondary care or tertiary care women attend (academic) hospitals to see an obstetrician or specialized 'clinical' midwife [172]. Recruitment procedures in the Netherlands involved 13 midwife practices in Amsterdam and surrounding areas and four (academic) hospitals. Irrespective of all efforts recruitment was low. Therefore, future studies might consider to recruit midwife practices and hospitals in other parts of the

Netherlands with higher obesity rates, such as the 'eastern' and 'southern' part of the Netherlands [338].

As previously discussed in **chapter 5,** one-third of the invited European women was willing to participate in the study. It is known that it are mostly the more motivated people who are willing to participate in a research project [175], but that it frequently are the persons who decline participation that might benefit the most from a lifestyle intervention [112]. The intervention method (motivational interviewing) is considered an effective strategy to use in health behaviour interventions for those unmotivated to change [128]. Therefore, more effort should be exerted to refer unmotivated women.

Generalizability

Externally validity is important to assess generalizability of findings [280]. The DALI study was conducted across nine European countries and included a varied population of pregnant women with a BMI ≥ 29. In addition to the heterogeneity, the programme was carried out under 'real life' conditions, therefore the results would seem transferable to other settings outside the research environment. However, the population in both the pilot (**chapter 4** [300]) and trial lifestyle DALI study (**chapter 6**) consisted mainly of higher educated (pilot 53%; trial 55%) women. Therefore, the results may not be directly generalizable to women with a lower educational level. Although, the developed intervention materials and the individual counselling approach were believed to be suitable and understandable for women with varied educational backgrounds.

Inclusion-exclusion criteria

Gestational diabetes mellitus according WHO and IADPSG criteria at baseline

Women with impaired glucose intolerance (IGT) at baseline assessment have not been excluded in previous studies. In DALI the women with early diagnosis of IGT comprised a high proportion of the consented women (22%). Exclusion of these women made DALI a true prevention trial, in which only women at risk of GDM but not diagnosed with GDM entered the study. The DALI study could investigate the actual incidence of GDM across Europe.

Diagnosis of IGT in early pregnancy and consequently treatment by health care providers was dependent on national guidelines, therefore it occurred that women were diagnosed for IGT within the DALI study but were not treated for IGT. It remains to be questioned if diagnosis of IGT according to the WHO and IADPSG is appropriate in early pregnancy [348], since the cut off points are based on research in mid-pregnancy [69]. Women were diagnosed with GDM at 24-28 weeks of gestation (usual care testing) and were treated from that time onwards. It could have been beneficial if treatment had started earlier. Therefore, more research on the group with IGT early in pregnancy is needed to appropriately advise usual practice.

Body mass index below 29

In DALI a BMI ≥29 kg/m^2, calculated with pre-pregnancy weight and measured height, was used as inclusion criteria, except when women clearly did not know their pre-pregnancy weight. In that case weight at first maternal care visit was used. If this was not available either the weight at the DALI baseline assessment would be used. Pre-pregnancy weight is based on self-reported weight, which is often an under-reporting of actual body weight [37]. Unfortunately, eight women with a BMI < 29 kg/m^2 based on self-reported pre-pregnancy weight should have been excluded. Six out of these eight women had a BMI above 29 kg/m^2 at the first DALI visit and were considered included into the pilot study. Additionally, in the vitamin D and lifestyle trial study this comprised six out of ten women. The decision to include everybody with a BMI above 29 kg/m^2 at baseline assessment irrespective of a lower pre-pregnancy BMI was based on the previous rules regarding unawareness of pre-pregnancy weight.

Focusing on women with a BMI of 29 kg/m^2 or above led to a population at higher risk for negative pregnancy outcomes [66,291], but reduced the amount of eligible women for the study. All overweight women (additional inclusion of women with BMI 25 to 28 kg/m^2) might potentially benefit from the delivered intervention. Especially, since information on GWG recommendations and risks due to their weight were not always provided to overweight women (**chapter 2** [159]), overweight women might gain more weight during pregnancy and retain more weight in the postpartum period. Only 11% of overweight and obese women are able to return to their pre-pregnancy weight within five years postpartum [76]. As the postpartum period is the pre-conceptional period of a subsequent pregnancy these might be entered with an increased bodyweight and BMI [76].

Intervention design

The provision of face-to-face lifestyle counselling fulfilled the need of a flexible approach compared to group sessions on fixed times and places. An individual approach gave the practitioner the opportunity to tailor all health information (within the defined group) exactly as needed by the participant, taking into account personal barriers, parity and culture. This design is definitely suitable for this population (**chapter 5**).

The DALI study design offered us an unique opportunity to investigate the separate and combined effect of physical activity and healthy eating in pregnancy, although without considering the preference of the participants. This means that, e.g. a woman was randomised to the HE group, while she preferred assistance with being more physically active throughout her pregnancy (or the other way around). Assigning the intervention by randomisation is basically in conflict with the primary value ‘free choice’ of MI as women in the HE group and PA group were constricted in their topics. It would be worthwhile to do a preference based study and compare outcomes.

Intervention uptake

The results within the DALI study, in favour of an HE intervention in the pilot study (**chapter 4** [300]) and in favour of a HE+PA intervention in the RCT [299], showed that the inclusion of a HE component is essential to maintain GWG. As is shown in **chapter 6** improvements in diet quality were obtained, although for physical activity this was less evident.

Considered from a physiological level, weight is a balance between energy intake and energy expenditure. The general advice for women is to consume 2000 kcal/day to maintain this balance. It takes an imbalance of 7000 kcal to lose one kilogram. Being physically active for 30 minutes equals about 350 kcal and 350 kcal equals about two glasses of sugary drinks.

This example illustrates that a huge time investment is required to lose 7000 kcal through physical activity alone (e.g. ten additional hours). Given that physical activity levels drop throughout pregnancy (**chapter 6**) rather than increase, it would at first glance seem almost impossible to limit GWG solely by physical activity. Furthermore, irrespective of pregnancy, a compensatory increase in energy intake as a result of more physical activity occurs frequently, since the body signals the brain to replace the burned calories [320].

Motivational mechanisms might also influence the association between physical activity and eating behaviour, as was shown in a study among non-pregnant overweight and obese women, in which a more intrinsically and autonomously motivation to exercise contributed also to improved eating behaviour [200]. Furthermore, a review among non-pregnant overweight and obese persons showed that a HE+PA compared to a PA intervention alone was more effective in the short (3 to 6 months) and long term (12 months) for weight loss [163]. However, the HE+PA intervention compared to a HE intervention alone was equally effective in the short term, but on the long term the HE+PA resulted in a greater weight loss [163].

An opportunity remains to optimize the physical activity part in lifestyle interventions. The skilfulness of the practitioner could play an important role (**chapter 5**), whereby correctly applying the principles of motivational interviewing is important (e.g. expressing empathy regarding barriers, develop discrepancy by evocating the personal benefits of physical activity, and supporting the autonomous decision making of the participant). Furthermore, as being more active in the beginning of pregnancy is associated with higher physical activity levels in late pregnancy [136], physical activity intervention programmes should start as early as possible. Other predictors of higher physical activity levels comprise those higher educated [104,109], with higher income, nulliparous and from Caucasian origin [109]. This stresses the importance to develop interventions especially for women with lower social economic status, from non-Caucasian origin and those already having one or more children.

Intervention delivery of motivational interviewing

In DALI, the level of MI proficiency was on average not according MI experts (**chapter 5**). However, low to medium levels of proficiency in MI from practitioners might still result in an (intervention) effect, although it is unclear if this is caused by a 'minimal' MI intervention or by other factors. Motivation to make behavioural changes is important [80]. It is possible that participants were highly motivated and considering change. As a consequence, they only needed minimal support. Participation in a research project (which explains sometimes a minimal effect of the control condition) or attention from a lifestyle coach might already be enough to implement the considered changes. Furthermore, participation in a research project is for some participants a reason to make the required changes, because otherwise their participation had been useless (external regulation). Thirdly, the willingness to live healthy for their unborn child, could have resulted in more motivation to implement changes compared to the general non-pregnant population (introjected regulation). Finally, perhaps small effects of MI were already displayed, but if MI was applied according expert opinion these effects would have been more robust [332] and sustainable across lifespan [129]. To obtain better MI levels of proficiency it is worthwhile for practitioners to pay more attention on the emersion of change talk of the participant (e.g. asking questions that elicit change talk and reflecting change talk when it occurs) and to emphasize the client's choice [14,232]. Contrary, certain MI-inconsistent behaviours such as confronting, advising without permission, raising concerns, or telling what to do (direct), could negatively impact and ruin the relationship with the participant [14,110,193]. Most of the research on working mechanisms of MI is conducted in studies targeting alcohol probation [278], this needs to be confirmed in other health promotion behaviours.

Outcome measures

A combination of measurement tools were used to evaluate characteristics and study outcomes, including anthropometrics, behavioural, biomedical (blood samples), process measures and questionnaires (**Chapter 3**). However, some considerations and limitations of the conducted measurements need to be discussed to interpret the results correctly:

Gestational weight gain

The approach to measure GWG differs across studies, some studies use pre-pregnancy weight while other studies use measured weight in early pregnancy [309]. In DALI the primary outcome GWG was based on the difference between measured weight at baseline visit (before 20 weeks) and the measured weight at the final visit (35-37 weeks), to prevent the influence of incorrect self-reported weight. However, the IOM guidelines for GWG refer to gestational weight gain defined as pre-pregnancy weight till weight at birth. The results regarding GWG need to be interpreted with some caution when comparing these to the IOM guidelines. On average across the whole DALI sample, the difference between self-reported weight and baseline weight comprised about two kilo.

Metabolic outcomes

The collected blood samples were both analysed in a local lab in each country (to check for inclusion/exclusion regarding GDM and to obtain results for usual care testing of GDM in mid-pregnancy) and in a central lab in Austria. The central blood results were used for analysis, to minimize differences caused by analysing technics and equipment in the different countries. However, the central values showed (minor) differences with the local values. These (minor) differences were for some participants in conflict with the inclusion-exclusion criteria. The inclusion/exclusion of participants regarding GDM needed to be based on local values due to the time delay of shipping the samples to Austria. In the pilot study 9% (13 out of 150) and in the trial study 14% (60 out of 435) should have been excluded for GDM at baseline based on the central lab results. On the other hand, 10% (5 out of 50) in the pilot and 32% (57 out of 176) in the trial study were wrongfully excluded based on the central lab results. This fact needs to be considered when interpreting the results of this study.

Physical activity

In DALI, physical activity is assessed both with an in pregnancy validated questionnaire and with accelerometers. The use of a combination of validated questionnaires and objective measures (e.g. accelerometer) make it possible to interpret the results with more certainty [252]. Especially, considering the limitations both tools have.

Self-reported questionnaires are biased, representing the individual's perception of her activity, and therefore frequently over-estimate physical activity levels [270]. Furthermore, women in the intervention group could report changes, because of having received the intervention message, but without a true change in behaviour. Another limitation relates to the calculation of intensities, which are based on metabolic equivalent of task (MET) values determined in a non-pregnant population, these MET values might be different as pregnancy progresses. Additionally, comparability among lifestyle intervention studies measuring physical activity with self-reported questionnaires is hindered by the usage of different instruments [330]. Evenson et al. (2011) provides an overview of all available self-reported instruments to measure physical activity in pregnancy and a list of considerations prior to selection, although no conclusive choice of the most suitable instrument was presented [95]. On the other hand an advantage of questionnaire data, which cannot be obtained by accelerometers, is the provision of more detailed data regarding the type of activity [64] (e.g. household activity, transportation, sports/exercise).

A limitation of accelerometers is the incorrect measurement of stationary exercise, upper-body movements and water-based activities [93]. Another limitation relates to the compliance over time [136,281], especially in late-pregnancy it becomes less comfortable to wear an accelerometer at waist placement. Additionally, body changes in midsection due to a progressing pregnancy could affect monitor placement and monitor tilt. Furthermore, walking velocity is slower in third trimester due the fact that altered body anthropometry gait patterns show a shorter step length and increased duration of the stance phase to improve gait stability [27]. And the resting metabolic rate, and thus total energy expenditure, increases as pregnancy

progresses [205]. All these factors should be considered when interpreting 'objective' data from accelerometers, especially in late-pregnancy.

There is now an innovative accelerometer available, the activPAL (PAL Technologies, Ltd, Glasgow, Scotland), which is designed to measure postural allocation [88]. This accelerometer can differentiate between lying/sitting versus standing or walking. The activPAL is worn over the quadriceps muscle with an adhesive plaster, and removal while sleeping is not necessary. The activPAL seems to offer a solution to deal with the issues of compliance and placement.

Process measure: fidelity

The DALI study distinguished itself by measuring the fidelity of the intervention through assessing all practitioners and intervention components, which frequently is lacking or conducted with non-validated instruments [219], as is discussed in **chapter 7** [158]. Explanations for the lack of MI fidelity are caused by 1) unawareness on how to conduct MI fidelity and consequently a lack of resources (e.g. lack of recorded sessions or money to invest in coding); 2) the use of non-validated or suitable coding instruments. The use of different quality assessments further hinders the comparability of studies; 3) the difficulty to acquire MI fidelity scores which are sufficient according expert opinion. Publication of a manuscript is more difficult with an intervention not showing a representative amount of MI and therefore authors might decide to only present the variables which are considered sufficient or not to present any of the variables at all (publication bias). It is important MI fidelity is presented in RCTs to distinguish among the quality of the conducted studies in future meta-analyses and reviews.

FUTURE DIRECTIONS

The worldwide high prevalence of overweight and obesity among reproductive women and consequently the high risk of developing GDM and diabetes type 2 stresses the need for prevention programmes that are feasible and attractive for individuals at risk. The next paragraphs discuss how future research could further assist in developing prevention programmes and how the clinical practice could implement the findings of our study.

IMPLICATIONS FOR FUTURE RESEARCH

The DALI study was a behaviour change prevention programme that intervened only during pregnancy. Even though pregnancy is an ideal time for interference as women are highly motivated by the health of their baby (**chapter 2** [159]), interference starting between 12-20 weeks gestation might be too late to change the already developed intra-uterine environment [45]. Additionally, based on research mostly conducted in rodent models it is known that paternal obesity affects the health of the offspring as well [204]. Therefore, lifestyle

interventions for couples prior to conception that continue in pregnancy (at least for the woman) could potentially have more effect than interventions during pregnancy alone. An easy to reach group for interventions prior to pregnancy might be couples that have trouble conceiving and are overweight or obese.

Furthermore, changing behaviour and maintaining the behaviour change throughout pregnancy is not always easy. Pregnancy specific barriers frequently experienced in the final trimester of pregnancy could result in a relapse. Therefore, future studies could consider to extent the intervention period beyond pregnancy and assist women in getting back to their pre-pregnancy weight and maintain their so learned new lifestyle long-term. Intervening in the post-partum period is especially valuable for women who are planning a subsequent pregnancy. They could reduce their increased risk for negative outcomes in this subsequent pregnancy if they manage to obtain a lower BMI.

The postpartum period is also an opportunity for women who were diagnosed with GDM, especially since testing for GDM occurs late in pregnancy (mostly as late as 28 weeks of gestation) and not much time is left in pregnancy to change lifestyle behaviours. A recent review showed that lifestyle interventions in the postpartum period can be effective in reducing type 2 diabetes and insulin resistance, and decrease bodyweight [122].

In attracting women to participate in lifestyle interventions it is important that the gap between research and practice is bridged. Obstetricians and midwifes need an active involvement in projects as a constant reminder of possible opportunities for their patients. Perhaps the intervention even needs to be embedded in the local practice facilities / hospitals. In the postpartum period infant welfare centres, involved in regular appointments for the new born baby, could fulfil this position.

MI is proven as a useful method for facilitating lifestyle behavioural change. However, it is important that practitioners delivering the intervention (irrespective if this done prior to conception, during pregnancy or in the postpartum period) are trained to the appropriate MI standards. As is shown in **chapter 5** quality varies among practitioners, even though they received the same training. Therefore more research on personal characteristics or specific qualities that lead to better uptake of MI could inform application processes. Future studies could consider hiring specialists in MI or consider providing the appropriate amount of training to lay personal involving individual feedback throughout the study period.

This study did not provide information on the long-term, for example a) if women were able to maintain their changes, returned to their pre-pregnancy weight or lost more weight postpartum; b) what the health effects were for children born to mothers with lower GWG; and further on c) if women provided a healthy environment for their children and set a standard for ways to live healthy in order to break the 'obesogenic cycle'. Moreover, it is interesting to learn how many women eventually developed type 2 diabetes mellitus and most

importantly in how many cases the development of this disease was prevented within the next 10 years.

RECOMMENDATIONS FOR PRACTICE

Implementation of a lifestyle intervention:
The DALI interventions did not lower the risk for GDM, although the HE intervention (chapter 4 [300]) and the HE+PA intervention [299] assisted women to prevent excessive GWG. Since gaining weight in adherence to the IOM guidelines leads to a lower risk of developing obesity after pregnancy [105] and since excessive GWG is an individual risk factor for negative outcomes during pregnancy [296], it is advised that counselling about appropriate GWG and how to obtain this needs to become part of the routine care of patients or discussed in additional sessions with a health care professional. However, before delivering the intervention practitioners need to be trained to a sufficient level of MI.

It is advised to follow at least a local 3-day MI training by a certified MI trainer and receive regular, but at least on four occasions [292], feedback on a real-life conversation with a patient. On the MI website (www.motivationalinterviewing.org) more information on training courses and MI trainers is available. William R. Miller and Stephen Rollnick have written already their third book about MI, with lots of practical examples and explanations [217] and in the appendix of this thesis the DALI study materials are made accessible. Furthermore, although only in the Dutch language, information on obesity, pregnancy and MI is recently published in a manual for the healthcare practitioner [331].

The effectiveness of MI increases with increasing skill level [332]. Therefore screening and selection on certain qualities during the application process of practitioners could be helpful, for example checks on empathy as this is an important predictor for MI skilfulness [220]. Furthermore, if within the same organisation more than one person is trained in MI this would allow for intervision meetings, in which discussion of difficulties with implementation of MI in practice could facilitate peer learning experience.

At an organizational level the decision to adopt MI interventions involves some complexity [345]. The willingness of a hospital to implement MI in usual care depends largely on the costs and the compensation from insurance companies. However, MI counselling on lifestyle and obesity related topics is not necessary linked to midwifery or obstetric departments alone. It is applied in primary care [226] and other hospital departments as well to improve either physical activity or healthy eating, such as in rheumatology [111], cardiology [178] or pulmonology [52]. Therefore to cover the additional treatment of these patients in a so called ‘lifestyle-clinic’ might give patients specialised lifestyle care by sufficiently trained practitioners and would give their usual health care provider the opportunity to focus solely on the provision of usual care treatment.

Resources for implementation of lifestyle interventions during pregnancy are readily translatable from the DALI intervention (see appendix). Nowadays internet has become an important source for information, e.g. regular newsletters or apps with growth status updates. However, the current online information frequently applies to women with a normal BMI. Obese and overweight women erroneously believe they are gaining weight in the healthy and safe range. This stresses the importance of correct GWG counselling by health professionals and the opportunity for the development of accurate online information for overweight and obese women. Furthermore, information technology may play a key role in developing a tool which is easy to consult by the women for specific information and to use for monitoring purposes.

Implementation of diagnostic criteria in the Netherlands

The WHO [11] has recently adopted the IADPSG criteria [10] for GDM. However, screening methods, diagnostic criteria and treatment is highly inconsistent across Europe [25]. Even within countries different approaches are used by midwife practices and hospitals. Consensus on screening for GDM is important to get timely diagnosis and appropriate treatment, and does not lead to unnecessary confusion and concerns with patients. To stress its importance once more, within DALI about 33% of the Dutch women were diagnosed (according the WHO and IADPSG guidelines) with GDM / impaired glucose intolerance before 20 weeks gestation. Currently evidence is lacking if early detection of GDM is as 'bad' for the mother and the child compared to detection of GDM in mid-pregnancy. This requires further research.

Conclusion:

The results of the DALI study indicated that a moderately intense physical activity and healthy eating lifestyle intervention could impact on GWG of overweight or obese women. This did not result in a lower incidence for GDM compared to a control condition, but might proof beneficial for returning to pre-pregnancy weight postpartum. Health care professionals interested to implement the DALI intervention into clinical practice should consider training their personnel to a sufficient motivational interviewing proficiency before counselling participants.

DALI 2.0 – implementation of the DALI intervention

Prevention of gestational diabetes mellitus and diabetes type 2

Facts:

- Overweight and obese women are at increased risk to develop gestational diabetes mellitus
- Several adverse outcomes for both mother and child have been associated with gestational diabetes mellitus
- A history of gestational diabetes mellitus is an additional risk in a subsequent pregnancy for developing gestational diabetes mellitus
- Gestational diabetes mellitus results in increased risk to develop type 2 diabetes for both mother and child

What does this thesis add:

- Women appreciated guidance on lifestyle behaviour throughout pregnancy
- The healthy eating intervention showed positive effects on gestational weight gain and fasting glucose compared to a physical activity intervention among 150 women across Europe
- The developed DALI intervention was well received by its target population
- Skilfulness in motivational interviewing of practitioners is important especially for delivering the physical activity intervention
- The interventions in DALI were able to improve dietary scores (in the HE and HE+PA group) and physical activity (in the PA group) during pregnancy.

What does DALI further add:

- In the combined (targeting both healthy eating and physical activity) a reduction of 2 kilo in gestational weight gain is found compared to a control group among 436 women across Europe
- No effect was found in any of the intervention groups compared to a control group on the metabolic parameters insulin and glucose or in the prevention of gestational diabetes mellitus among 436 women across Europe

How to move forward?

- Implementation of the DALI lifestyle intervention in usual practice by specifically trained lifestyle coaches
- Arrangement of regular supervision and intervision of the lifestyle coaches to maintain motivational interviewing skill at an appropriate level
- Continue the lifestyle counselling sessions in the postpartum period to prevent an increase of weight in between pregnancies and to enter a subsequent pregnancy with a lower body mass index
- Involvement of the partner if he is overweight or obese to aim for a family approach and facilitate a healthy environment for the children to grow up in
- Early detection and management of gestational diabetes mellitus

It is important that we aim to disrupt the mother-offspring vicious 'obesogenic' cycle