KU LEUVEN

FACULTEIT GENEESKUNDE
BIOMEDISCHE WETENSCHAPPEN

Evaluatie van de kennis rond zwangerschapsdiabetes en evaluatie van de (groeps)educatie voor zwangerschapsdiabetes: de ELENA studie

Evaluation of knowledge regarding gestational diabetes and evaluation of (group) education for gestational diabetes: the ELENA study

Masterproef voorgedragen tot het behalen van de graad van Master in de biomedische wetenschappen door

Caro MINSCHART

Promotor: Dr. Katrien BENHALIMA
Promotor: Prof. dr. Chantal MATHIEU

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PREFACE

This master's thesis includes an extensive evaluation of the knowledge of women with gestational diabetes about their condition and of (group) education for gestational diabetes, and has been written to fulfill the graduation requirements for the Master of Biomedical Sciences at the University of Leuven. I was engaged in conducting clinical research and writing this thesis from September 2017 to June 2018.

My path to completing the master's program in Biomedical Sciences was one with many bends and bumps, and I would not have succeeded in traveling this road without the help of many. I would like to take this opportunity to thank a number of people who helped me to bring this thesis to a successful conclusion. First of all, I wish to thank the University of Leuven, the Faculty of Medicine and in particular my promotor, Dr. Katrien Benhalima, who gave me the opportunity to perform my thesis at the Department of Clinical and Experimental Endocrinology and to immerse myself into the subject of gestational diabetes. Thank you, Dr. Benhalima, for giving me the confidence to further develop this project and for always making time for my questions and concerns, despite your busy schedule. I would also like to express my gratitude to prof. Dr. Chantal Mathieu, head of the department of Clinical and Experimental Endocrinology, for providing the facilities that were needed to conduct this research.

I am especially grateful to diabetes educator Peggy Calewaert, who made me feel welcome in the diabetes team starting from day one of my internship. Thank you for taking me under your wings and sharing all the knowledge that you possess on gestational diabetes and beyond. All other members of the team, in particular the diabetes educators and dietitians, deserve a sincere thank you as well for their support and contribution in the ELENA study. Not only the professional help, but also the daily support and kindness of everyone in this team, has made this a year to never forget. Furthermore, I wish to thank all participants who were willing to invest their time in completing the questionnaires for my research. Without their cooperation, it would not have been possible to perform this master's thesis.

In conclusion, I would like to use this opportunity to thank a number of people who were not involved in my master's thesis in the strict sense, but still played a very important role in finishing my degree in Biomedical Sciences. First and foremost, I want to express my infinite gratitude to my parents and stepparents for their unconditional support during my entire KU Leuven career. They gave me the opportunity to expand my academic career with a master's degree in Biomedical Sciences after finishing a master in Rehabilitation Sciences, which finally made me feel like I ended up where I belong. In particular, I would like to thank my mother and sister for always being a listening ear and sounding board, and for providing the much needed distraction during difficult moments. Finally, I want to thank Pieter for his loving support during this adventure. Thank you for your endless patience in dealing with all of my insecurities and doubts. You're my favorite place to go when my mind searches for peace.

Caro Minschart Leuven, May 2018

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LIST OF ABBREVATIONS

ACHOIS	Australian Carbohydrate Intolerance Study in Pregnant Women
ACOG	American College of Obstetricians and Gynecologists
ADA	American Diabetes Association
BEDIP-N	Belgian Diabetes in pregnancy Study-North
BMI	Body Mass Index
CES-D	Center for Epidemiologic Studies Depression
DAWN	Diabetes Attitudes, Wishes and Needs
DTSQs	Diabetes Treatment Satisfaction Questionnaire – status version
EBCOG	European Board & College of Obstetrics
EFW	Estimated fetal weight
EM	Ethnic minority
EMB	Ethnic minority background
FIGO	International Federation of Gynecology and Obstetrics
FPG	Fasting Plasma Glucose
GCP	Good Clinical Practice
GCT	Glucose Challenge Test
GDM	Gestational Diabetes Mellitus
GGOLFB	Groupement des Gynécologues Obstétriciens de Langue Française de Belgique
GI	Glycemic Index
HAPO	Hyperglycemia and Adverse Pregnancy Outcome
IADPSG	International Association of Diabetes and Pregnancy Study Groups
IDF	International Diabetes Federation
IGT	Impaired glucose tolerance
IQR	Interquartile range
LGA	Large-for-gestational age
NDDG	National Diabetes Data Group
NICU	Neonatal intensive care unit
NPH	Neutral protamine Hagedorn

OAD	Oral antidiabetic agent
OGTT	Oral Glucose Tolerance Test
PCOS	Polycystic Ovary Syndrome
QOL	Quality of life
SD	Standard deviation
SGA	Small-for-gestational age
SMBG	Self-monitoring of blood glucose
SPE	Study of Perinatal Epidemiology
STAI	Spielberger State-Trait Anxiety Inventory
T2DM	Type 2 Diabetes Mellitus
WHO	World Health Organization

ABSTRACT

BACKGROUND

The management of GDM is a labor-intensive discipline, in which the global increase in GDM prevalence poses challenges to maintain high-quality care. A valuable solution could be the organization of group education. The ELENA study therefore aimed to evaluate women's satisfaction about (group) education and treatment, their knowledge about GDM and whether the diagnosis is associated with feelings of depression and anxiety.

METHODS

This monocentric prospective and observational cohort study enrolled 175 women with a recent diagnosis of GDM. Participants attended two education sessions, with the first session offered as a group education for Dutch-speaking women. An individual follow-up session was planned within two weeks. Participants completed questionnaires before and after the education measuring sociodemographic characteristics, knowledge about GDM, satisfaction about education and treatment, and feelings of depression and anxiety.

RESULTS

Of all participants, 86 received their first session in group and the remaining 89 participants received an individual session. Patients were overall satisfied with the content and duration of both the first and second session. 97.7% was very confident in the given advice and 59.1% thought the advice was not too strict. Moreover, knowledge of participants about their condition considerably improved after education was given. Feelings of depression and anxiety were apparent prior to the education, but declined afterwards. 90.5% of all women receiving group education were satisfied with the group size and 77.4% found that group education fulfilled their expectations.

CONCLUSION

Women diagnosed with GDM were overall satisfied with (group) education and had a better understanding of their condition after education. Group education could be a valuable alternative to offset many practical problems associated with an increase in GDM prevalence.

1. INTRODUCTORY LITERATURE OVERVIEW

1.1 Gestational Diabetes Mellitus

1.1.1 DEFINITION AND EPIDEMIOLOGY

The world today is being confronted with a continuous increase in the prevalence of diabetes, with nearly half a billion people living with this noncommunicable disease (1). In their latest report, The International Diabetes Federation (IDF) estimated that this number may even rise up to 693 million people by 2045 if no further action is taken (1). Gestational diabetes mellitus (GDM) is a well-known predictor for type 2 diabetes mellitus (T2DM) in later life, with literature showing up to one-third of women with T2DM having a history of GDM (2). In addition, offspring of mothers with GDM have a higher risk of obesity, metabolic syndrome and T2DM, a phenomenon that contributes to the increasing prevalence of T2DM worldwide (3). Effective prevention and treatment strategies directed at women who experienced GDM could therefore have a significant impact on the increasing burden of noncommunicable diseases such as T2DM.

GDM is a frequent medical complication during pregnancy and is historically defined as 'any degree of glucose intolerance with onset or first recognition during pregnancy' (4). The worldwide prevalence of GDM varies between 3-14% of all pregnancies, depending on the population and on which screening strategy and diagnostic criteria for GDM were used (4). The latest report of the IDF indicated that 21.3 million or 16.2% of live births in 2017 had some form of hyperglycemia in pregnancy, of which 86.4% was due to GDM, 6.2% due to diabetes detected prior to pregnancy, and 7.4% due to other types of diabetes (including type 1 and type 2 diabetes) first detected in pregnancy (1). Traditional risk factors for GDM include advanced maternal age, overweight and obesity, ethnicity, family history of diabetes and prior history of GDM (5–8). On the other hand, some studies have reported protective effects of the adoption of a healthy diet and active lifestyle on the development of GDM (8,9).

1.1.2 PATHOPHYSIOLOGY OF GDM

During pregnancy, adaptations in the glucose metabolism take place in order to promote fetal development while maintaining adequate maternal nutrition (10). Hormonal factors such as human placental lactogen, growth hormone, progesterone, cortisol and prolactin are known to counteract the effects of insulin. Increasing release of these reproductive hormones causes interference with insulin receptor signaling in the second and third trimester of pregnancy, thereby initiating a decrease in insulin sensitivity in the peripheral tissues (11).

In normal pregnancy, maternal euglycemia is maintained by an augmentation in maternal insulin secretion. However, if the capacity of the pancreatic beta-cells is surpassed and the body is unable to upregulate insulin production relative to the degree of insulin resistance associated with pregnancy, GDM develops (12). Moreover, Catalano et al. established that women developing GDM already display subclinical metabolic dysfunction prior to conception, predisposing them to impaired insulin secretion during pregnancy (13). Insulin resistance is further exacerbated during pregnancy in these individuals, which results in mild hyperglycemia, corresponding to the clinical diagnosis of GDM (13). From the second trimester of pregnancy, the fetal pancreas starts to respond to maternal hyperglycemia by secreting insulin, causing fetal hyperinsulinemia (14). The combination of maternal and fetal

hyperglycemia on the one hand, and fetal hyperinsulinemia on the other hand, is known to cause an increased risk for adverse pregnancy outcomes for both mothers and their offspring (14,15).

1.1.3 SHORT-TERM FETAL AND MATERNAL COMPLICATIONS

The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study was the first large study showing certain risks of adverse outcomes associated with degrees of maternal glucose intolerance less severe than overt diabetes mellitus (15). Short-term risks for women diagnosed with GDM include increased rates of cesarean delivery, premature delivery and preeclampsia (16). Moreover, the rate of preeclampsia appears to be associated with the severity of GDM (17). The most common adverse neonatal outcomes are fetal macrosomia (birth weight > 4 Kg) and being large for gestational age (LGA, birth weight > 90 percentile adjusted for sex and parity) (15,18). Babies born to diabetic mothers have a three-fold higher rate of macrosomia compared to normoglycemic controls (14). They appear to have larger shoulder and extremity circumferences, a decreased head-to-shoulder ratio, significantly higher body fat and thicker upper-extremity skinfolds, making them more vulnerable to birth injuries such as shoulder dystocia and brachial plexus trauma (14). Data from the Australian Carbohydrate Intolerance Study in Pregnant Women (ACHOIS) confirmed a positive relationship between the severity of maternal fasting hyperglycemia and the risk of shoulder dystocia, with a 1-mmol increase in fasting glucose leading to a 2.09 relative risk of shoulder dystocia (19). Other well-known adverse neonatal outcomes are neonatal hypoglycemia, hyperbilirubinemia and admission to intensive neonatal care (16). Women with GDM on insulin represent a particular high risk population, since rates of LGA infants and cesarean sections appear to be higher in insulin-treated women compared to diet-treated women (20).

1.1.4 LONG-TERM CONSEQUENCES OF GDM

Shortly after delivery the glucose metabolism of women with GDM normalizes, but the underlying beta-cell dysfunction often persists (21). This finding could explain why women with a history of GDM are found to have at least a seven-fold increased risk of developing T2DM compared with women who had a normoglycemic pregnancy (22). Recent research conducted at UZ Leuven has shown that approximately 42% of women with GDM, diagnosed on the basis of the 2013 WHO criteria, experienced glucose intolerance in early postpartum (23). The most important risk factors for early progression to glucose intolerance after GDM include maternal age, pre-pregnancy weight, early GDM diagnosis, insulin treatment during pregnancy, ethnicity and biochemical risk factors such as the fasting plasma glucose (FPG) on the diagnostic oral glucose tolerance test (OGTT) during pregnancy (24). Follow-up after delivery is critically important to timely detect glucose intolerance after pregnancy and presents opportunities to delay T2DM or to prevent complications associated with its diagnosis (25). Not only women with GDM, but also their offspring are at increased risk of developing a number of long-term consequences related to maternal GDM, such as obesity, the metabolic syndrome, T2DM and impaired insulin sensitivity and secretion (26). Studies indicate that an in utero hyperinsulinemic environment is associated with offspring's increased risk of being overweight and developing a metabolic syndrome (3,27,28). Moreover, a large Danish follow-up study demonstrated that offspring born to women with GDM have an eight-fold increased risk of developing T2DM or pre-diabetes compared with a background population at the age of 22 years (29). If the offspring is female, an additional risk exists of developing GDM in their own future pregnancy (30). Taking all of this evidence in consideration, GDM is a perfect example of the 'fetal origins of adult disease' hypothesis, stating that glucose intolerance during pregnancy predisposes the offspring to a higher risk of childhood obesity, impaired glucose

tolerance in adolescence, and overt diabetes and hyperlipidemia in later life (31). This phenomenon creates a vicious cycle in which women with GDM give birth to babies with epigenetic changes, who are in turn prone to develop metabolic diseases later in life (32).

1.2 Screening and diagnosis of GDM

In 1964, Dr. John O'Sullivan established the first criteria for assessing the upper limit of glycemic normality in pregnancy (33). Even though these criteria served as a starting point for all future research in the field of GDM, there is to date no uniform consensus regarding the screening and diagnosis of GDM. Controversies include the selection criteria for biochemical testing, the performance of the test and the glycemic thresholds that should be used (34). The main problem with the O'Sullivan criteria is the fact that these criteria were chosen to identify women at high risk of developing T2DM after pregnancy rather than being based on an increased risk for adverse perinatal outcomes (31). Meanwhile, the HAPO study has established a continuous and graded relationship between maternal hyperglycemia below levels diagnostic of diabetes and the risk of adverse perinatal outcomes, irrespective of other risk factors (16). In 2008, The 'International Association of Diabetes and Pregnancy Study Groups' (IADPSG) organized an international conference to review the results of the HAPO study. Based on these findings, a consensus statement was reached in 2010 for a new screening strategy and diagnostic criteria for GDM (35). The IADPSG criteria are unique in the sense that these are the first diagnostic criteria for GDM based on the risk of developing adverse perinatal outcomes. A universal one-step screening strategy is advised in this consensus statement, with a 2-h 75g OGTT performed between 24 and 28 weeks of gestation. The recommended cut-off values for the FPG, 1-h and 2-h OGTT reflect an increase in risk with 75% for the development of a birth weight > 90 percentile, a C-peptide in the baby > 90 percentile and a percentage body fat in the baby > 90 percentile (35). One abnormal glucose value is sufficient for the diagnosis of GDM, making these criteria much more stringent. Table 1 provides an overview of the new IADPSG criteria and other commonly used criteria (31).

Table 1. Overview of the different diagnostic criteria for GDM

	3-h 100g OGTT NDDG (1979)	3-h 100g OGTT Carpenter and Coustan (1982)	2-h 75g OGTT WHO (1999)	2-h 75g OGTT IADPSG (2010)
Fasting	≥ 105 mg/dl	≥ 95 mg/dl	≥ 126 mg/dl	≥ 92 mg/dl
1 h	≥ 190 mg/dl	≥ 180 mg/dl	/	≥ 180 mg/dl
2 h	≥ 165 mg/dl	≥ 155 mg/dl	≥ 140 mg/dl	≥ 153 mg/dl
3 h	≥ 145 mg/dl	≥ 140 mg/dl	/	/
Number of abnormal values required for diagnosis	≥ 2	≥ 2	≥ 1	≥ 1

NDDG: National Diabetes Data Group, OGTT: Oral Glucose Tolerance Test, WHO: World Health Organization, IADPSG: International Association of Diabetes and Pregnancy Study Group

As the diagnostic cut-off values are more stringent, adoption of the new IADPSG criteria will lead more often to the detection of milder forms of GDM and might therefore present an opportunity for these women to receive more timely an appropriate treatment (36). Moreover, the use of uniform diagnostic criteria corresponds well with the idea to encourage a uniform international approach in the field of GDM (35). However, considerable controversy remains regarding the implementation of the IADPSG recommendations as this will lead to an important increase in the number of women diagnosed with GDM, thereby creating a substantial increase in workload and associated costs (37). Studies comparing outcomes of one-step versus two-step approaches have been inconsistent to date (38). More research is needed to investigate the most cost-effective screening strategy for GDM (39).

Several national and international organizations currently have different recommendations regarding the screening and diagnosis of GDM. In 2013, the World Health Organization (WHO) decided to adopt the IADPSG criteria for the diagnosis of GDM (40). The IADPSG criteria are since then commonly called the '2013 WHO criteria for GDM'. The American Diabetes Association (ADA) leaves the choice between a one-step screening strategy with a 2-h 75g OGTT using the IADPSG criteria, or a two-step screening strategy with a non-fasting 50g glucose challenge test (GCT) and if abnormal (1-h glucose value ≥ 140 mg/dl) followed by a 3-h 100g OGTT using either the NDDG criteria or the Carpenter and Coustan Criteria (38). In Europe, most national societies now recommend the use of the 2013 WHO criteria for GDM but this is still largely debated, mainly due to the disadvantages of increased work load and healthcare costs and the danger of increased medicalization of antenatal care related to the use of these criteria (36,41). In 2015, The 'European Board & College of Obstetrics and Gynaecology' (EBCOG) has responded to this controversy by recommending the new WHO diagnostic criteria for GDM when screening between 24 and 28 weeks of pregnancy (36). Nevertheless, no clear recommendation was made concerning the use of universal or selective screening strategies in this proposal (36). A survey from the EBCOG on screening for GDM in Europe demonstrated that the majority of national societies still recommend screening based on risk factors and that only a minority recommends the use of a universal one-step approach in the screening and diagnosis of GDM (42).

Inconsistencies in recommendations for screening and diagnosis of GDM are also apparent in Belgium. While a Flemish consensus was reached in 2012 to continue to recommend the two-step screening strategy (43), the 'Groupement des Gynécologues Obstétriciens de Langue Française de Belgique' (GGOLFB) decided to adopt the IADPSG recommendations for a universal one-step screening strategy in the French-speaking part of Belgium (44). A survey conducted in the northern part of Belgium by Benhalima et al. further confirmed that there is a large variation in screening strategies for GDM, with only 25% of the participating centers adopting the new IADPSG criteria (39). In order to evaluate different screening strategies for GDM based on the 2013 WHO criteria, The Belgian Diabetes in pregnancy Study (BEDIP-N) was started in 2014 (45). This multi-centric prospective cohort study assessed the IADPSG screening strategy in combination with risk questionnaires and a 50g GCT to define the most cost-effective screening strategy for GDM (45). Meanwhile, the BEDIP-N study is completed and the first results show now that if a two-step screening strategy is applied with a GCT and OGTT, the cut-off for the GCT should be reduced to ≤ 130 mg / dl at least to ensure a sensitivity of ≥ 70%. In this case, an OGTT could be avoided in 65% of all women compared to the one-step screening strategy with the 75g OGTT alone (46). Awaiting a new Flemish consensus on screening and diagnosis of GDM at the end of 2018, the endocrinology department of UZ Leuven currently relies on the IADPSG criteria in combination with a two-step screening strategy, performing an OGTT only if the GCT is abnormal with a threshold of 140 mg/dl after 1 hour.

1.3 Management of GDM

Various studies have confirmed that treatment of women with GDM results in a lesser degree of perinatal complications, mainly in the frequency of macrosomia, shoulder dystocia and preeclampsia (47–50). In contrast, research concerning long-term metabolic effects on offspring of women treated for GDM is limited and recent studies could not show any treatment effect of GDM on future poor metabolic outcomes of these children (49). Further research in this field is therefore warranted.

The management of GDM relies on a quintet approach including maternal education, diet modification, exercise, pharmacology and fetal surveillance (51). Initial treatment of GDM always involves non-pharmacological approaches such as medical nutrition therapy, weight management, physical activity and glucose monitoring (38). If lifestyle measures are insufficient to reach and maintain glycemic targets, pharmacological therapy should be added (38).

1.3.1 NUTRITION THERAPY AND WEIGHT MANAGEMENT

Nutritional management is the cornerstone in the treatment of GDM, with the intention of achieving normal maternal blood glucose levels and reducing the risk of accelerated fetal growth (52). Dietary advice is given in order to avoid excessive maternal weight gain, thereby limiting the risk of adverse pregnancy outcomes as well as the risk for the mother to develop T2DM later in life (52–54). No specific recommendations are available for gestational weight gain in pregnancies complicated by GDM, but the Institute of Medicine (IOM) revised guidelines for weight gain during pregnancy are also applicable in this context (Table 2) (55). Recent investigations in obese women with pregestational diabetes even suggest that a more stringent restriction of gestational weight gain less than 5 Kg is associated with a more proportionate birth weight and less perinatal morbidity (56). Based on these data, it might be safe to advise obese women with T2DM to gain less than 5 Kg during pregnancy. This is therefore now advised in UZ Leuven.

Nutritional therapy involves an individualized diet strategy to achieve maternal euglycemia and control weight gain throughout pregnancy, while taking personal and cultural eating habits, physical activity, blood glucose measurements and the expected physiological effects of pregnancy on both the mother and the fetus into account (12). To date, there is little evidence supporting different dietary approaches in the treatment of GDM (57). A recent review exploring strategies in the nutritional management of GDM suggested that a diet higher in complex carbohydrate and fiber, low in simple carbohydrates and lower in saturated fat may be effective in reducing postprandial hyperglycemia, thereby preventing aggravated insulin resistance and excess fetal growth (58). Another meta-analysis studied the efficacy of dietary interventions on maternal or neonatal outcomes in patients with GDM and found that a low glycemic index (GI) diet was associated with less frequent insulin use and lower birth weight (59). Remarkably, other diets such as a total restriction diet and low carbohydrate diets could not produce similar benefits (59). It might therefore be concluded that not the percentage of carbohydrates in itself, but especially their composition is the most important aspect in diet management for women with GDM.

Most guidelines recommend to limit carbohydrate intake to 35 – 45% of the total amount of calories with a minimum daily intake of 175 g carbohydrates to enable normal development of the fetal brain (12,18,60–62). In practice, it is recommended to distribute the carbohydrate intake throughout the day in three major meals and 2 – 4 snacks to limit postprandial glycemic fluctuations (62).

Table 2. 2009 IOM guidelines for weight gain during pregnancy

Prepregnancy BMI (Kg/m²)	Single pregnancy weight gain (Kg)	Twin pregnancy weight gain (Kg)
Underweight: < 18,5	12.5 – 18.0	No guidelines available
Normal weight: 18,5 - 24,9	11.5 – 16.0	17.0 – 25.0
Overweight: 25 - 29,9	7.0 – 11.5	14.0 – 23.0
Obese: ≥ 30	5.0 – 9.0	11.0 – 19.0

BMI: Body Mass Index

1.3.2 PHYSICAL ACTIVITY

Benefits of physical activity during normal pregnancy have been established many years ago (63–65), but few interventional trials have been published regarding the efficacy of physical activity in the management of GDM. Despite the fact that the results of most of these trials are based on small sample sizes, they demonstrated an improvement in glucose levels through exercise (66–69). A recent Cochrane review confirmed the beneficial effect of exercise on blood glucose levels, but could not find any differences in other maternal or neonatal outcomes (70). Further research is required, comparing different types of exercise interventions with control groups or with other exercise interventions to define the best possible exercise strategy for women with GDM.

Unless there is a medical condition which may be exacerbated during exercise or a relative contra-indication for participating in aerobic exercise during pregnancy, women with GDM are generally advised to engage in moderate physical activity (71). Physical activity can be performed by means of aerobic exercise such as walking, jogging or swimming. It is recommended that these exercises are conducted with no more than two consecutive days between aerobic exercise sessions and for a duration of 30 minutes per session. In addition to aerobic exercise, resistance strength training and flexibility exercises are also safe and beneficial in the management of GDM. With regard to resistance training, a minimum frequency of twice a week and ideally three times a week on non-consecutive days should be pursued (51,71). The American College of Obstetricians and Gynecologists (ACOG) further advises against the exercise of contact sports such as ice hockey, boxing, soccer, and basketball or activities with a high risk of falling such as skiing, surfing, off-road cycling and horseback riding (71).

Physical activity is not only beneficial during the treatment of GDM but has a strong protective effect on its development as well, thus having the possibility to disrupt the vicious circle involving GDM, childhood and adulthood obesity, and T2DM (8,9). A meta-analysis from 2011 demonstrated that women with the highest pregestational activity level experienced a 55% reduction in risk of developing GDM compared to women with the lowest activity level (9). Physical activity in early pregnancy was also associated with a significant 25% lower risk of GDM for women engaged in high levels of physical activity (9).

1.3.3 BLOOD GLUCOSE MONITORING

Self-monitoring of blood glucose (SMBG) by means of a glucometer should be initiated in all women with GDM in order to reduce the risk of pregnancy complications (12). Little evidence from RCTs exists regarding the optimal daily frequency and timing in relationship to a meal for SMBG (12). The general recommendation is to measure the blood glucose four-times daily, performed at fasting state and at 1-hour or 2-hour intervals after every meal (12,38,60,62). Glycemic targets endorsed by the Fifth International Workshop-Conference on GDM and adopted by most guidelines are fasting ≤ 95 mg/dl, 1-h postprandial ≤ 140 mg/dl and 2-h postprandial ≤ 120 mg/dl (72). Meanwhile, a meta-analysis reviewing glycemic targets in pregnant women with diabetes, demonstrated that a cut-off point of ≤ 90 mg/dl for FPG was associated with a lower risk of macrosomia in the offspring of women with GDM (73). Based on these findings, the Endocrine Society suggested in their latest guideline on diabetes and pregnancy to strive for an FPG target of ≤ 90 mg/dl if this can be safely achieved without undue hypoglycemia (60). The frequency of SMBG is often being decreased by health care providers when nutritional management and physical activity are successful in achieving goals for metabolic control (72). In UZ Leuven, women diagnosed with GDM are asked to monitor their blood glucose levels initially four days weekly. When life-style measures are successful in attaining glycemic targets, SMBG may be reduced to two days per week. When glycemic targets are not reached with life style modifications, treatment with insulin has to be started, at which point continuous daily monitoring of blood glucose becomes necessary.

1.3.4 PHARMACOLOGICAL THERAPY

The use of blood-lowering pharmacological therapy is required in women with GDM if target glucose levels cannot be reached by means of life style interventions alone. In that case, subcutaneous insulin is considered the treatment of choice because it does not pass through the placenta (38,60,62). Short-acting insulin analogues lispro and aspart are both safe to use in pregnant women with diabetes and should be administered when postprandial glucose values exceed the recommended glycemic targets (12,60,72,74). To treat fasting hyperglycemia, either insulin neutral protamine Hagedorn (NPH) or the long-acting insulin analogue detemir are approved for use in pregnancy (12,60,75).

Although insulin continues to be the first-line treatment for women with GDM, there are a few disadvantages related to its use. Insulin therapy is associated with an increased risk of hypoglycemia and weight gain (76), which could contribute to increased rates of adverse pregnancy outcomes such as LGA infants and cesarean sections (20). In addition, insulin treatment is often experienced as a heavy burden for women with GDM, resulting in negative experiences with emotional impacts lasting beyond pregnancy (77). These women often express a desire to have other options in the management of GDM (77). Increasing evidence suggests that oral antidiabetic agents (OAD) like metformin and glyburide may be a possible treatment option for women with GDM (76,78,79). However, the use of glyburide seems to be associated with an increased risk of neonatal hypoglycemia, high maternal weight gain, high neonatal birthweight and macrosomia (79). The ‘Metformin in Gestational Diabetes’ (MIG) trial showed that the use of metformin was not associated with increased perinatal complications compared to the group treated with insulin and that women preferred the use of metformin compared to a treatment with insulin. However, almost half of the women in the metformin group required additional insulin during pregnancy (76). OADs for the treatment of GDM cannot yet be recommended as more evidence is needed with regard to the risks and benefits of their use, especially concerning the long-term outcomes in children exposed to OADs in utero (80).

1.3.5 OBSTETRICAL MANAGEMENT

Women with well-controlled, diet-treated GDM without other maternal complications have no increased risk of stillbirth (62). The ACOG therefore suggests that antepartum fetal surveillance may not be necessary in this subgroup. In those women who have poor glycemic control or who are treated medically with insulin or OADs, initiation of fetal surveillance is recommended at 32 weeks of gestation (18,62). The International Federation of Gynecology and Obstetrics (FIGO) further recommends clinical and sonographic growth assessment every 2 – 4 weeks from diagnosis until delivery, since macrosomia is the most frequent complication of GDM (12,15). Unfortunately, most monitoring tools for fetal growth are inaccurate, with an error margin of approximately 15% (12). Despite the fact that rates of cesarean section are high in women with GDM, the condition as such is not an indication for a cesarean delivery (81). Most guidelines agree, however, that scheduled cesarean delivery may be justified if the estimated fetal weight (EFW) exceeds 4500 g in a pregnancy complicated by diabetes (12,18,62). In patients with well-controlled, uncomplicated diabetes and reassuring fetal conditions, a wait-and-see policy until the estimated date of delivery may be considered (82). In order to avoid neonatal hypoglycemia immediately after childbirth, maternal glucose concentrations are checked repeatedly during labor (83). Postpartum blood glucose levels usually return to normal rapidly, but it is recommended to measure plasma glucose concentrations in the first days following the delivery to detect undiagnosed overt diabetes (83).

1.3.6 POSTPARTUM MANAGEMENT

Women with a history of GDM are at high risk of developing health problems in later life. GDM might be the best well-known predictor for the subsequent development of T2DM, as it is estimated that approximately one-third of women with T2DM may have had previous GDM (2). In addition, a Danish follow-up study revealed that the metabolic syndrome occurred three times as frequent in women with a history of GDM, compared with an age-matched control group (84). According to the Coronary Artery Risk Development in Young Adults (CARDIA) study, women with a history of GDM are at greater risk of early subclinical atherosclerosis even before the onset of diabetes and metabolic diseases (85). Both the ACOG and the ADA recommend that all women with GDM undergo a 75g OGTT within 12 weeks postpartum using non-pregnancy criteria to test for persistent diabetes or prediabetes, and that these women have lifelong screening for the development of glucose intolerance (38,62). In practice, however, very low postpartum screening rates are achieved, with only 30 to 50 % of women with a history of GDM receiving a postpartum OGTT (86). This is a missed opportunity in a high-risk population to prevent progression to T2DM, since research has shown that both intensive life style interventions and metformin therapy are capable of delaying or preventing diabetes in women with impaired glucose tolerance (IGT) and a history of GDM (87). Several small studies have shown the effectiveness of postpartum reminders in increasing screening rates for women with GDM, but very few studies focused on the efficacy of reminders after the first year postpartum (88). The Belgian ‘Sweet Pregnancy’ project, an initiative of the Flemish Diabetes Liga financed by the Flemish Government, was set up to sensitize women with GDM and their care providers with regard to the increased risk of T2DM, and to promote postnatal follow-up with their general practitioner (89). Women registered in the ‘Sweet Pregnancy’ recall register receive annual reminders for a FPG screening test with their general practitioner in order to timely detect and treat glucose intolerance. The preliminary results of the project indicated that one third of women with GDM developed either prediabetes or diabetes over a six-year period (86). This high percentage emphasizes the importance of timely detection and treatment of glucose intolerance in this high-risk population.

1.4 The necessity of education in the management of GDM

Education is an essential part in the management of GDM. Treatment of GDM should always start with education about medical nutrition therapy, SMBG, physical activity, and weight management. The concept of self-management is thereby crucial to achieve good maternal and neonatal outcomes (90). Hence, diabetes educational programs for women with GDM should be organized in order to help them cope with their condition during pregnancy. GDM management is already a labor-intensive discipline, involving a multidisciplinary team of endocrinologists, obstetricians, midwives, diabetes educators and dietitians (37). The increase in GDM poses challenges to health care services in controlling this increasing burden, and additional resources will be needed to support these women as adequately as possible during their pregnancy and beyond (37). A valuable solution to cope with this increasing workload could be the organization of group education sessions. To evaluate the multidisciplinary group education for the management of GDM, the ELENA study was initiated at the University Hospital Gasthuisberg, UZ Leuven.

1.4.1 GROUP OR INDIVIDUAL EDUCATION

Mensing et al. demonstrated in 2003 that group education is an efficient and cost-effective alternative to individual education in the organization of diabetes care (91), but few studies have investigated the benefits of group education for women with GDM. A study investigating multidisciplinary group education in women with GDM, found that group sessions were associated with a reduction in carbohydrate consumption and an increase in physical activity level among women with GDM (92). It also appeared to be a cost-effective alternative, since the implementation of group sessions resulted in a combined clinical time saving of 8 – 28 hours per week (92). Another observational study in the United States established that women with GDM in group prenatal care required less insulin treatment (26% vs 63%, $p < 0.001$), attended post-partum follow-ups more often (92% vs 66%, $p = 0.002$), and underwent more often a postpartum glucose screening (76% vs 48%, $p < 0.001$) compared to women who received conventional obstetrical care (93). However, no significant differences were found in obstetrical or neonatal outcomes. Factors associated with group education such as learning from the experience of peers, a greater connection with health care providers and a motivating group dynamic may partially explain these beneficial results (93). Parikh and colleagues recently confirmed the positive influence of group care on glycemic control in a prospective cohort study comparing 20 pregnant diabetic women in group care to 28 patients in standard prenatal care (94). Moreover, women in group care had higher patient satisfaction scores (94). A recent study demonstrated the benefits of group education sessions delivered by a specialized diabetes midwife and a dietitian on women's knowledge of GDM, but made no comparison with individual education sessions (95). Additional high-quality studies in this research area are necessary to evaluate the cost-effectiveness and feasibility of group education compared with conventional individual education sessions in the management of GDM.

1.4.2 TREATMENT SATISFACTION

Although the attitudes and beliefs of women with GDM about their management are known to be critical factors in influencing self-management behavior, they have been little studied (90). Parallel research on T2DM subjects showed higher adherence to treatment with higher treatment satisfaction (96). A Malaysian study among women with GDM established that 73.5% of their participants displayed

adequate treatment satisfaction and, more important, that glycemic control depended on the patients' attitude towards their condition and treatment satisfaction (97). In New Zealand, a qualitative study revealed a high treatment satisfaction among patients with GDM receiving antenatal diabetes care (98). More evidence on patient satisfaction with treatment and (group) education for GDM could be useful in tailoring the content and delivery of (group) education sessions to this particular population.

1.4.3 KNOWLEDGE OF GDM

Education is a cornerstone in the treatment of women with GDM, as the management of this condition is mainly based on active measures undertaken by the patient herself. Knowledge about GDM might result in better adoption of a healthy lifestyle, better treatment adherence and better self-management. However, literature related to the evaluation of knowledge among women with GDM regarding their condition is scarce. A Malaysian study among 175 women with GDM demonstrated that higher knowledge about GDM is related to better glycemic control (99). Furthermore, educational level seemed to be a critically important factor in the comprehension of GDM according to a study exploring the knowledge about GDM of a multi-ethnic group of women with GDM (100). Poorer understanding of GDM could therefore be related to lower educational standards, but also to lower health literacy in general (100). Moreover, ethnic and cultural differences seem to influence health literacy level as well, thus having a significant impact on self-management of GDM (7). There are indications that women from an ethnic minority background need greater resources to better understand their condition in order to improve treatment adherence (7). Health care providers involved in the education of women with GDM must therefore always be aware of different health literacy levels and cultural variation among women with GDM. Additional information regarding the knowledge and awareness of women with GDM about their disease could help taking these aspects into account as much as possible in the organization of (group) education.

1.4.4 FEELINGS OF DEPRESSION AND ANXIETY ASSOCIATED WITH THE DIAGNOSIS OF GDM

Depression and GDM are both common disorders during pregnancy and have often been studied separately. However, there is a paucity on studies examining outcomes in women who have both. Depression is a relatively common condition in women with GDM, with nearly 15% of women with GDM experiencing symptoms of depression during their pregnancy (101). A cross-sectional study found that 20% of women with GDM had significant symptoms of depression compared with 13% of women without GDM, but this result was not statistically significant (102). They also suggested that a history of depression may be a risk factor for the development of GDM (102). Depression can lead in turn to poor management of GDM, thus increasing the risk of adverse pregnancy outcomes such as macrosomia and neonatal hypoglycemia (103). In addition, women with GDM who underwent a cesarean delivery and had greater gestational weight gain, have a greater risk of developing postpartum depression as well, which may interfere with lifestyle change efforts in the postpartum period (104). Health care providers should therefore be aware of the risk of antenatal depression when treating women with GDM and should regularly screen for depression in order to timely provide appropriate care (103).

Moreover, the diagnosis and management of GDM may also be associated with an increase in maternal anxiety and stress levels. A recent survey revealed that more than half of the participants with GDM, especially those on insulin, were distressed about the diagnosis, struggled with their dietary management and displayed feelings of anxiety concerning the risk of pregnancy complications (105).

Another study compared anxiety levels of women diagnosed with GDM with glucose-tolerant women and found higher levels of anxiety in women with GDM after their diagnosis (106). However, these feelings of anxiety decreased throughout pregnancy and no differences in anxiety scores were seen between the two groups around 36 weeks of pregnancy and in the postpartum period (106). These results may indicate that education and reassurance by health care providers is successful in dissipating anxiety and distress experienced by women with GDM.

2. OBJECTIVES OF THE ELENA STUDY

The overall objective of the ELENA study is to evaluate the multidisciplinary (group) education for the treatment of GDM.

The specific aims are:

1. To evaluate the knowledge regarding GDM of women with a recent diagnosis of GDM and the impact of the education on their understanding of GDM.
2. To evaluate the satisfaction with the (group) education of women with GDM using a structured education program.
3. To evaluate treatment satisfaction of women with GDM.
4. To evaluate whether the diagnosis of GDM is associated with feelings of depression and anxiety and whether this can be mediated by the education given to these women.
5. To analyze baseline and follow-up data of women with GDM concerning glycemic control, gestational weight gain and pregnancy outcomes.
6. To evaluate the frequency of insulin use in pregnancy for GDM.

3. MATERIALS & METHODS

3.1 Study design

The ELENA study is a monocentric prospective and observational cohort study conducted in UZ Leuven. This study is performed in compliance with the principles of the Declaration of Helsinki (2008), the principles of Good Clinical Practice (GCP) and all applicable regulatory requirements. The study protocol has been approved by the local Ethics Committee of UZ Leuven on 15/09/2015 (ClinicalTrials.gov Identifier: NCT02528162). First recruitment occurred on 07/10/2015. From there on, individual education sessions for the management of GDM have been replaced as much as possible by structured group education sessions given by a certified diabetes educator and/or dietitian. Individual education is still provided for women who are not willing or able to attend the group education.

Women with GDM were given a leaflet with general information about GDM at the time of their diagnosis and received an appointment for their first education session, planned within two weeks after their diagnosis. At the start of the first education session, women received information about the ELENA study. Upon agreement to participate, an informed consent form was signed prior to the education. Informed consent was given for participation in the observational study with gathering of data through questionnaires and extraction of relevant data from medical electronic files.

3.1.1 STRUCTURED (GROUP) EDUCATION PROGRAM

Since October 2015, the endocrinology department of the UZ Leuven replaced the first individual education session for the management of GDM by a structured group education session as much as possible. For this purpose, a structured PowerPoint presentation was developed in consultation with an endocrinologist specialized in GDM, diabetes educators and dietitians. The structure and content of this presentation was evaluated on a regular basis and adapted if necessary to the most recent guidelines and recommendations. For non-Dutch speaking patients, the presentation was translated in French and English. Dutch speaking women received an appointment to attend the group education session with a maximum of six participants, weekly given by a diabetes educator and a dietitian on Monday morning. Non-Dutch speaking women attended an individual education session given by a diabetes educator on Monday or Friday afternoon. The same structured PowerPoint presentation was used both for the individual and group education.

3.1.2 THE COURSE OF THE EDUCATION SESSIONS

Within two weeks after the diagnosis of GDM, women attended the first education session, given by a certified diabetes educator and/or dietitian based on the structured PowerPoint presentation. The group education was organized as a 1.5 to 2 hour session, while the individual session lasted on average 1 to 1.5 hour. Several important aspects related to GDM were discussed during this first session, such as the pathophysiology, risk factors, consequences and diagnosis of GDM. Subsequently, a large part of the education focused on the treatment of GDM, which relies primarily on diet management, physical activity and SMBG. The recommended weight gain was also discussed in more detail, as well as the various carbohydrate sources and the importance of limiting rapid-absorbed carbohydrates throughout pregnancy. Other topics included the follow-up after pregnancy, the long-term risks associated with

GDM and the benefits of breastfeeding. After the presentation, the diabetes educator explained and demonstrated the use of the blood glucose meter for the SMBG. Patients were asked to measure and register their blood glucose values four times per day (fasting and two hours postprandial after each meal) for four days per week until their next appointment with the dietitian. In addition, they received a seven-day diet journal to write down their nutritional regimen. All women were advised to register in the 'Sweet Pregnancy' project, a recall system supported by the 'Diabetes Liga' and financed by the Flemish Government to stimulate postpartum screening for glucose intolerance in women with GDM (89). At the end of the first education session, women received the handouts of the presentation, a brochure with information on physical activity, a glucose monitoring diary, a seven-day diet journal, some recipes, material for SMBG and an appointment for the individual follow-up session with the dietitian.

The follow-up session was planned within one to two weeks after the first education and took on average 30 to 40 minutes. During this session, the dietitian analyzed and discussed the patient's seven-day diet journal together with the glucose monitoring diary. Women received further advice regarding their gestational weight gain and dietary habits. If glycemic targets were met (fasting < 95 mg/dl and 2 hours postprandial < 120 mg/dl), women were advised to continue to perform SMBG two times per week until their delivery. Further follow-up of glycemic values occurred through mail, phone or by attending the diabetes outpatient clinic every two weeks. In case of persistent inadequate glycemic control, treatment with insulin was started in consultation with an endocrinologist. The type of insulin was chosen according to the glycemic values. Short-acting insulin analogues Novorapid or Humalog were administered in case of elevated postprandial glycemic values. Long-acting human insulin was only indicated if fasting glycemic values were too high. Women on insulin were asked to perform daily seven-point glucose profiles and a consultation with an endocrinologist was planned every two weeks until the delivery.

Based on the obstetrical policy, it was recommended to induce labor at 40 weeks and six days at the latest. After delivery, glycemic values of the mother were monitored during 48 hours regardless of whether insulin was needed during pregnancy or not. All women received a visit from the diabetes educator at the maternity ward, with a short educational conversation about the importance to continue a healthy lifestyle and with a scheduled appointment for a 2-h 75g OGTT three months postpartum. This appointment could be postponed to maximum six months after delivery if women were still breastfeeding at three months.

3.2 Selection of study participants

Women were invited to participate in the ELENA study after their diagnosis of GDM based on the 2-h 75g OGTT with the use of the IADPSG criteria (35). The study started recruiting participants from UZ Leuven in October 2015 and aims to recruit 200 women with GDM over a four year period. Up to this date, 175 participants have already been recruited. The eligibility criteria for participating in the study are listed in Table 3.

Table 3. Inclusion and exclusion criteria for the ELENA study

Inclusion criteria	Exclusion criteria
• Pregnant women ≥ 18 years old • Recent diagnosis of GDM	• Women who received bariatric surgery • Women diagnosed with pregestational diabetes or diabetes during early pregnancy

GDM: Gestational diabetes mellitus

3.3 Study procedures

3.3.1 STUDY VISITS

Women with GDM were recruited by a diabetes educator for participation in the ELENA study within two weeks after their diagnosis of GDM. These women received two education sessions, of which the first was given by the diabetes educator (and dietitian in case of group education) and the second by the dietitian alone. After these two sessions, additional follow-up sessions with the dietitian could be planned if needed. A general overview of the different education sessions is given in Figure 1.

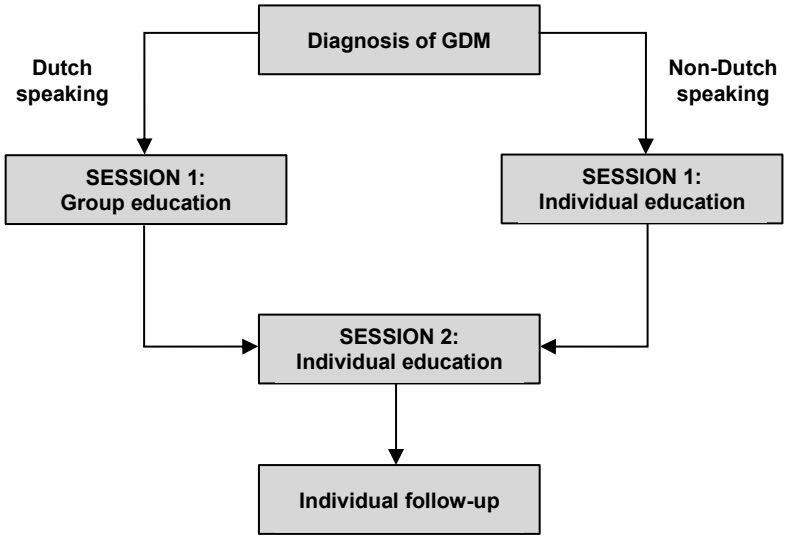


Figure 1: overview of the education sessions

Treatment and follow-up of study participants did not differ in any way from the routine care for women with GDM. More specific, there was no medical intervention, no extra visits, nor extra blood tests compared to the normal routine. The only difference was the completion of self-administered questionnaires by the study participants before the first education session and after the first and second education session. These questionnaires aimed to evaluate the education of GDM and the knowledge that these women have about GDM. For this purpose, the questionnaires measured sociodemographic characteristics of the subjects, knowledge of GDM, feelings of depression and anxiety associated with the diagnosis of GDM, and the satisfaction of the education and the treatment. It took about 10 to 15 minutes at each point in time to fill in these questionnaires. All questionnaires were translated into French and English for non-Dutch speaking participants. An overview of the questionnaires administered at each education is given in Table 4.

- Questionnaire I: general characteristics

This self-designed questionnaire, administered at the start of the first education session, was used to collect general sociodemographic information from the study participants, such as education level, ethnicity, and financial and marital status.

- Questionnaire II: knowledge of GDM

The aim of this self-designed questionnaire was to examine the knowledge of the participants regarding GDM. It contains questions about the knowledge of risk factors and consequences of GDM, about the diagnosis of GDM, and about treatment and follow-up after delivery. As shown in Table 4, this questionnaire was given at each point in time.

- Questionnaire IIIa and IIIb: satisfaction of the education

Self-designed questionnaires were created to evaluate the satisfaction of the education (IIIa and IIIb) and whether treatment goals could be achieved (IIIb). Questionnaire IIIa was administered after the first education session and questionnaire IIIb after the second education session. Both questionnaires start with a question using a Likert scale, evaluating the participant's satisfaction with twelve items that were discussed during the presentation. Women could score each statement from 'strongly disagreeing' to 'strongly agreeing' or 'not knowing'. The next questions are designed to evaluate women's perceptions on the duration of the group session, the advantages and disadvantages of group education and the size of the group. The questionnaire also provides an open question to write down feedback or comments on the education. In questionnaire IIIb, an additional question is included regarding patient satisfaction on accomplishing life style modifications in the week following the first education session.

- Questionnaire IV: CES-D questionnaire on depression

The 'Center for Epidemiologic Studies Depression' (CES-D) questionnaire is a well-known tool for measuring feelings of depression in the general population (107) and is validated to use in pregnancy (108). It consists of 20 items, with each item being scored between 0 and 3 on a four-point Likert scale, from respectively 'rarely or none' to 'almost all the time'. Total score on the CES-D questionnaire can range from 0 to 60, with a score of ≥ 16 being suggestive for clinical depression (108). Participants were asked to fill out the questionnaire before the first as well as after the first and second education session.

- Questionnaire V: STAI questionnaire on anxiety

The validated six-item short-form of the Spielberger State-Trait Anxiety Inventory (STAI-6) questionnaire produces results that are similar to those obtained using the full 20-item STAI and has often been used to measure state anxiety level when time for completing questionnaires is limited (109). The six items in the short version are being scored from 'very much' to 'not at all' with a four-point Likert scale, giving a total score ranging from 6 to 24, with a higher score indicating a greater level of anxiety (110). Similar to the CES-D questionnaire, this questionnaire was completed at each point in time.

- Questionnaire VI: DTSQs questionnaire on treatment satisfaction

The Diabetes Treatment Satisfaction Questionnaire – status version (DTSQs) is a validated tool for measuring satisfaction with diabetes treatment regimens in people with diabetes, which is frequently used in clinical trials and has been perceived as suitable for assessing outcomes of diabetes care (111). Study participants were requested to fill out this questionnaire after the second education. The questionnaire consists of eight items. Six of them are designed to measure satisfaction with current treatment, treatment convenience, treatment flexibility, understanding of diabetes and recommendation of the treatment to other diabetic patients. The scores for these items range from 0 meaning 'very dissatisfied' to 6 meaning 'very satisfied' with a total score varying from 0 to 36, thus higher scores referring to greater treatment satisfaction. Item 2 and 3 are related to perceived frequency of hyperglycemia and hypoglycemia. These two items are analyzed separately with scores varying between 0 ('none of the times') and 6 ('most of the times') as well (97).

Table 4: Overview of the questionnaires of the Elena study

	Before the first education session	After the first education session	After the second education session
General questionnaire I	x		
Questionnaire II on the knowledge of GDM	x	x	x
Questionnaire IIIa on the satisfaction of the education		x	
Questionnaire IIIb on the satisfaction of the education			x
Questionnaire IV: CES-D on depression	x	x	x
Questionnaire V: STAI questionnaire on anxiety	x	x	x
Questionnaire VI: DTSQs questionnaire on treatment satisfaction			x

3.3.2 COLLECTION OF DATA FROM THE MEDICAL ELECTRONIC FILES

Data from the participants' medical electronic files are collected during pregnancy, at delivery and three months postpartum:

- General clinical data: Maternal age, body length, body weight and BMI at first prenatal visit and at delivery, gestational weight gain, family history of diabetes, smoking, alcohol intake during pregnancy, history of hypertension and dyslipidemia, history of PCOS, history of prediabetes, history of GDM and parity.
- Data about the diagnosis: Results of FPG, GCT, OGTT and Hba1c, the time between GCT and OGTT, the (in)tolerance for OGTT, gestational age at the diagnosis of GDM, timing and result of the postpartum OGTT.
- Data about the treatment: The time between diagnosis and the start of the education, treatment with corticoids, if glycemic targets are met with lifestyle measures, the need of insulin during pregnancy, when insulin was started and which type of insulin was started (short acting and/or long acting).
- Maternal pregnancy outcome data: Gestational hypertension (blood pressure ≥ 140/90 mmHg), preeclampsia, preterm delivery (< 37 weeks of gestation) and cesarean section (planned cesarean sections and emergency sections).
- Neonatal pregnancy outcome data: Gender, birth weight, macrosomia (birth weight > 4 Kg), LGA (birth weight > 90 percentile adjusted for sex and parity) (112), SGA (birth weight < 10 percentile adjusted for sex and parity) (112), shoulder dystocia, Apgar score (at five minutes) and admission at the neonatal intensive care unit (NICU).

3.4 Statistical procedures

Statistical analyses were performed by means of IBM SPSS Statistics version 24. No power calculation was performed for this pilot-study. Normally distributed, continuous data were shown as mean and standard deviation (SD) whereas non-normally distributed data were displayed as median an interquartile range (IQR). Categorical data were presented as counts and valid percentages. Chi-square test for independence was used to determine the differences in scores on the knowledge questionnaires between women in group education and in individual education. To evaluate the effect of the education on the knowledge of GDM, proportions of knowledge questionnaires were compared before the first and after the second education using the McNemar test. The Mann-Whitney U test was used to determine the difference between the two groups concerning feelings of anxiety as well as education and treatment satisfaction. To compare the presence of clinical depression between the two groups, the Chi-square test for Independence was performed. The McNemar test and Wilcoxon Signed Rank test were used to examine respectively feelings of depression and anxiety before the first and after the second education. A p-value of <0.05 (two-sided) was considered significant.

4. RESULTS

4.1 Participants

Since October 2015, 321 women were diagnosed with GDM of which 175 participated in the ELENA study. Women with GDM who did not participate in the study despite meeting the inclusion criteria were mainly women who did not understand English, Dutch or French well enough to complete the questionnaires, women who received the education during a hospitalization or women who did not wish to participate. Of all participants, 86 received their first education session in group, whereas the other 89 participants followed an individual session. 65 of all participants following the individual education were Dutch-speaking but didn't attend the group session because they were the only one planned for the group session (n=45) or because they were not available at the time of the group session (n=20). The remaining 24 participants following individual education were English-speaking (n=20) or French-speaking (n=4). Over the entire period, 37 group sessions were given with an average of 3 participants per group (Figure 2).

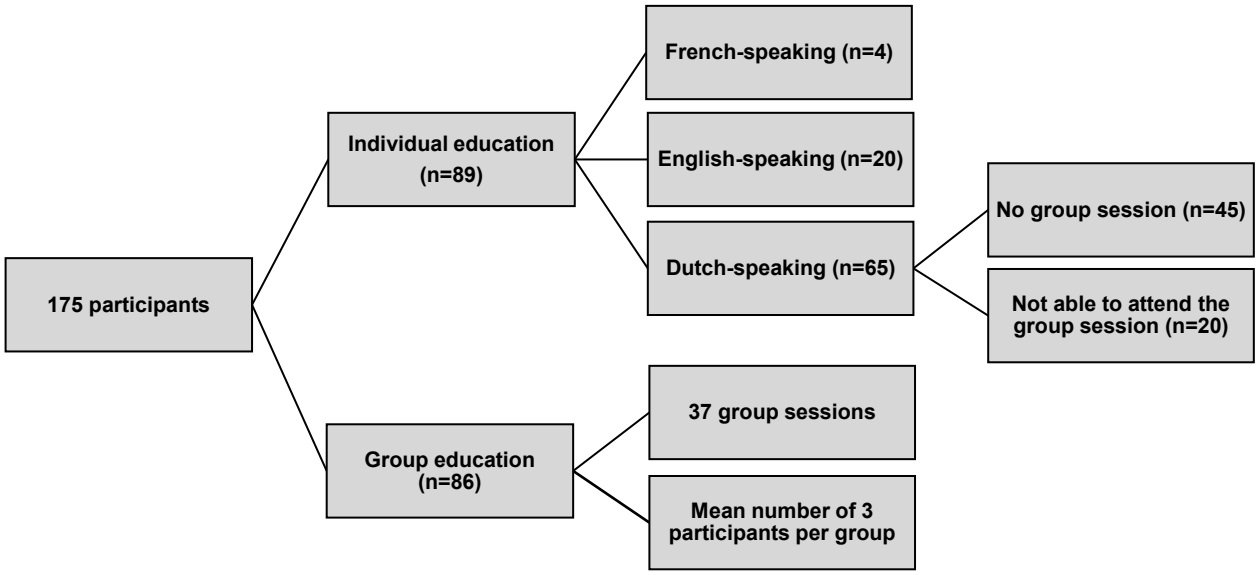


Figure 2: overview of participants in the ELENA study

4.2 General characteristics

An overview of the general characteristics of women participating in the study is given in Table 5. Mean age was 32.5 (± 5.1) years, 30.2% (51) had overweight and 27.9% (47) was obese at the first prenatal visit. Of all participants, 12.5% (13) had a history of GDM, 19.1% (33) had a first-degree relative with T2DM and 23.1% (40) had an ethnic minority background (EMB), of which 16 had an Asian background, 8 were Black-African, 7 North-African, 4 Middle-East, 2 Turkish and 1 had a Latin-American background. The majority of women in this study cohort obtained a higher degree diploma (70.9%) and had a paid job (80%). Only 14 women (8.2%) were single.

Table 5: General patient characteristics

	N	Result
Age (mean)	173	32.5 (± 5.1)
% overweight at first prenatal visit *	169	30.2% (n=51)
% obese at first prenatal visit **	169	27.9% (n=47)
% EMB	**40**	**23.1%**
Asian	16	9.2%
Black-African	8	4.6%
North-African	7	4%
Middle-East	4	2.3%
Turkish	2	1.2%
Other	2	1.2%
Latin-American	1	0.6%
% first degree relative with T2DM	173	19.1% (n=33)
% with a history of GDM	104	12.5% (n=13)
% multiparity***	173	24.9% (n=43)
% primigravida******	173	38.2% (n=66)
% high secondary diploma *******	173	83.8% (n=145)
% higher degree diploma ********	168	70.9% (n=119)
% paid job	170	80% (n=136)
% single *********	171	8.2% (n=14)

EMB: ethnic minority background; T2DM: type 2 diabetes; GDM: gestational diabetes

* Overweight at first prenatal visit: BMI between 25 – 29.9 Kg/m². ** Obesity at first prenatal visit: BMI ≥ 30 Kg/m². *** Multiparity: > 1 delivery. **** Primigravida: first pregnancy. ***** High secondary diploma: High secondary general (59.5%, n=103), high secondary technical (13.3%, n=23), high secondary professional (11%, n=19). ****** Higher degree diploma: University (41.7%, n=70), higher education outside the University short type or bachelor (24.4%, n=41) and long type or master (4.8%, n=8). ******* Single: Never married (6.4%, n=11) or divorced (1.8%, n=3).

4.3 Screening, diagnosis and treatment characteristics

Table 6 gives an overview of the screening, diagnosis and treatment characteristics of the study cohort. The GCT and OGTT were performed at respectively a median of 25.0 (23.0 - 27.0) and 26.0 (24.0 - 28.0) weeks of pregnancy. Mean HbA1c at time of the OGTT was 5.2% (± 0.4). GDM education started at a median of 27.0 (25.0 - 29.0) weeks. Of all women with GDM, 18.4% (27) needed insulin treatment during pregnancy, which was started at a median of 29 (26 - 32) weeks. All women with GDM were offered postpartum screening with a 75g OGTT, of which 87.5% (112) had effectively undergone the 75g OGTT. This test was performed at a median of 14.0 (11.0 - 17.0) weeks after delivery. Of all women who received the postpartum OGTT, 39.8% (43) had glucose intolerance.

Table 6: Screening, diagnosis and treatment characteristics of the study cohort

	N	Result
Screening		
Week of GCT (median)	107	25 (23 – 27)
Week of OGTT (median)	163	26 (24 – 28)
HbA1c, mean in %	160	5.2 (± 0.4)
Treatment		
Week of start education (median)	171	27 (25 – 29)
% insulin	147	18.4% (n=27)
Week of start insulin (median)	24	29 (26 – 32)
OGTT postpartum		
% present at OGTT	128	87.5% (n=112)
Time after delivery (median in weeks)	111	14 (11 – 17)
% Abnormal OGTT	108	39.8% (n=43)

GCT: glucose challenge test; OGTT: oral glucose tolerance test

4.4 Pregnancy outcomes

As shown in Table 7, women delivered at a median of 39.0 (37.0 - 41.0) weeks of pregnancy with a median gestational weight gain of 8.7 Kg (1.3 - 16.1) . 10.7% of all women had gestational hypertension and 6.7% preeclampsia. 16 women (10.7%) delivered preterm and 46 women (30.9%) delivered with a cesarean section. Table 8 shows the neonatal pregnancy outcomes, with 2% of all the babies having shoulder dystocia, 6.1% needing a transfer to the NICU and 2.8% having an Apgar score < 7 after 5 minutes. Macrosomia, LGA and SGA were present in respectively 5.4%, 10.9% and 10.2% of all babies.

Table 7: Maternal pregnancy outcomes

	N	Result
Total weeks of gestation (median)	149	39 (37 – 41)
Weight gain during pregnancy (median in Kg)	148	8.7 (1.3 – 16.1)
% gestational hypertension	149	10.7% (n=16)
% preeclampsia	149	6.7% (n=10)
% preterm delivery *	149	10.7% (n=16)
% cesarean section	149	30.9% (n=46)

* Preterm delivery: < 37 weeks

Table 8: Neonatal pregnancy outcomes

	N	Result
Mean birth weight (Kg)	142	3.3 (± 0.6)
% macrosomia	148	5.4% (n=8)
% LGA	147	10.9% (n=16)
% SGA	147	10.2% (n=15)
% shoulder dystocia	149	2% (n=3)
% NICU transfer	147	6.1% (n=9)
% Apgar score < 7 after 5 minutes	143	2.8% (n=4)

LGA: large for gestational age; SGA: small for gestational age; NICU: neonatal intensive care unit

4.5 Knowledge about GDM

All women were asked to fill in a questionnaire concerning their knowledge about GDM. The first question identified patients' expectations about sources of information on the subject of GDM (Figure 3). Health care providers such as a diabetes educator (63.4%), obstetrician (58.9%), dietitian (56.0%), midwife (45.1%), general practitioner (34.9%) and diabetes doctor (30.3%) were frequently reported sources of information. Other sources were the internet (37.7%) and flyers (29.1%), using websites such as Sweetbee, Zoet Zwanger, UZ Leuven and Info Medical to gather information. Remarkably, family (12%) and friends (9.1%) were only occasionally indicated as a source of information.

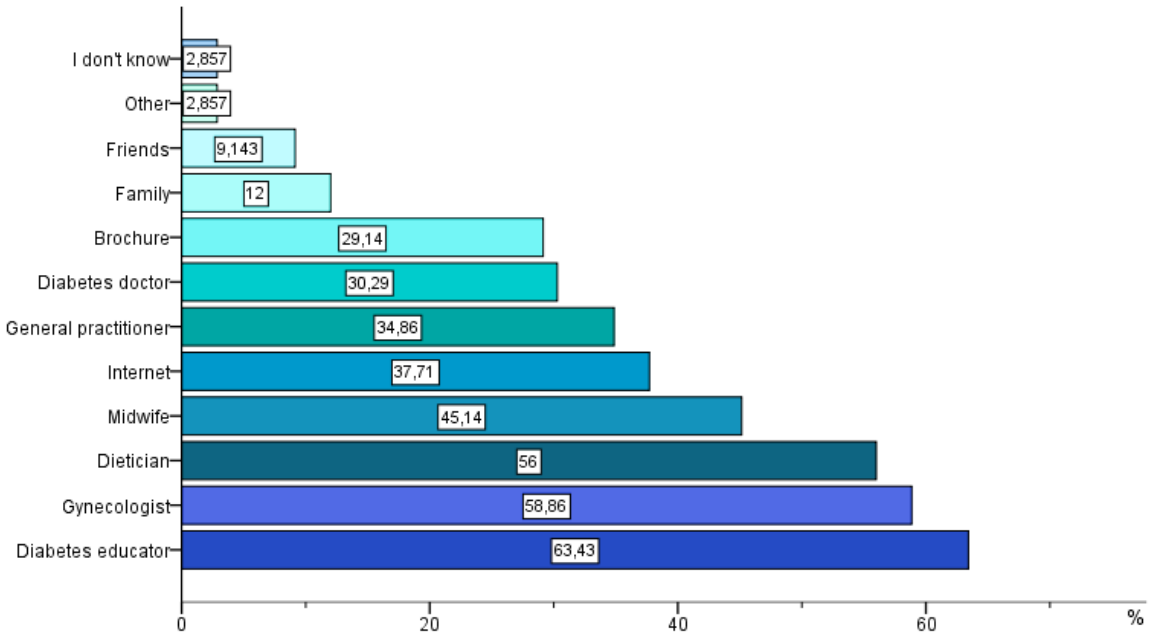


Figure 3: overview of reported sources of information by participants

4.5.1 KNOWLEDGE ABOUT GDM BEFORE THE FIRST AND AFTER THE SECOND EDUCATION SESSION

General response rates on the knowledge questionnaire were compared before the first and after the second education session to evaluate the knowledge about GDM of women with a recent GDM diagnosis and the impact of the education on their understanding of GDM. Only women who completed the questionnaire at both time points (n=138) were included for this analysis. Response rates on the correct answers are illustrated in Table 9. Women generally had a good knowledge of the topic 'diagnosis of GDM' prior to the first education, which even improved afterwards. Knowledge about the risk factors for GDM was already adequate before the first education session for the items 'overweight before pregnancy', 'GDM during a previous pregnancy' and 'first degree relative with diabetes', with response rates of 76.1% (105), 69.6% (96) and 72.5% (100) respectively. On the other hand, only 35.5% (49) and 49.3% (68) of the respondents selected 'too much weight gain during pregnancy' and 'age > 30 years' as a risk factor, but response rates improved significantly to 53.6% (74) and 62.3% (86) after education was given (p=<0.0001 and p=0.005). Concerning the complications of GDM, knowledge on all items significantly increased. Notably, only 29 women (21.2%) identified preeclampsia as a complication before the first education session, however this number improved significantly to 105 (76.6%) after the second education session (p<0.0001). With regard to the treatment of GDM, knowledge about topics such as 'the initial treatment of GDM', 'measuring the blood sugar levels' and 'treatment with insulin' improved significantly after the second education session. However, only 18.8% of all women indicated in advance that fruits should be restricted. After the second education session, this percentage increased significantly (p<0.0001), but 44.9% still could not select the correct answer. The majority of women knew at the start of the first education session that breastfeeding is good for the general health of the baby (58.7%), but only 26.1% knew that this could also lower the risk of diabetes and obesity later in their child's life. After the second education the response rate on this question increased significantly (p=0.002), but even then only a minority (39.9%) could indicate the correct answer. In terms of follow-up, only 52 women (37.7%) were aware of their strongly increased risk of 50% to develop T2DM within 10 years after delivery. This number increased to 113 women (81.9%) after the second education and this difference was statistically significant (p<0.0001).

4.5.2 KNOWLEDGE ABOUT GDM IN GROUP EDUCATION VERSUS INDIVIDUAL EDUCATION

In order to compare the knowledge about GDM between participants in group education and those in individual education, response rates on the knowledge questionnaire after the first education session were summarized for both groups (Table 10). Women showed an overall good knowledge of most topics, with only a few significant differences between the two groups. For example, women in group education seemed to recognize risk factors of GDM more often than women in the individual session, in particular the risk factors 'overweight before pregnancy' (92.9% vs. 78.4%, p = 0.013) and' first degree relative with diabetes' (88.1% vs. 73.9%, p = 0.03). With respect to the treatment of GDM, women in group education were more often aware that insulin is only started if dietary change and physical activity is insufficient compared with women in the individual session (75.0% vs. 59.1%, p=0.04).

Table 9: Comparison of the general response rates on the knowledge questionnaire before the first and after the second education session

	Before 1st education (n=138)	After 2nd education (n=138)	P-value
Diagnosis of GDM			
When is GDM diagnosed? 24 – 28 weeks	96.4% (133)	98.6% (136)	0.453
How is GDM diagnosed? Based on a fasting blood collection in combination with drinking a sugar solution	81.2% (112)	87.0% (120)	0.186
Risk factors of GDM			
It's more likely to develop gestational diabetes if you:			
Are overweight before pregnancy	76.1% (105)	87.0% (120)	**0.004**
Gain too much weight during the pregnancy	35.5% (49)	53.6% (74)	**<0.0001**
Have had GDM during a previous pregnancy	69.6% (96)	79.0% (109)	**0.011**
Have a first degree relative (parents, brothers or sisters) with diabetes	72.5% (100)	79.0% (109)	0.093
Your age is > 30 years	49.3% (68)	62.3% (86)	**0.005**
Complications of GDM			
What are the consequences for the baby if the treatment of GDM is insufficient?			
Too high birth weight of the baby	84.1% (116)	97.8% (135)	**<0.0001**
Increased risk of diabetes for the baby later on	59.4% (82)	75.4% (104)	**0.002**
Increased risk of overweight for the baby later on	49.3% (68)	66.7% (92)	**0.001**
What are the risks for you if the treatment of GDM is insufficient?			
An increased risk for a difficult delivery	75.7% (103)	91.2% (124)	**<0.0001**
An increased risk for preeclampsia	21.2% (29)	76.6% (105)	**<0.0001**
An increased risk for a cesarean section	63.5% (87)	89.1% (122)	**<0.0001**
Treatment of GDM			
How is GDM initially treated after diagnosis?			
Dietary change and increasing physical activity	58.0% (80)	76.8% (106)	**<0.0001**
Insulin is only started if dietary change and physical activity is insufficient	52.9% (73)	61.6% (85)	0.120
Which food products do you have to restrict if you have GDM?			
Pie	87.0% (120)	94.9% (131)	**0.013**
Fruits	18.8% (26)	55.1% (76)	**<0.0001**
Sugared soda	93.5% (129)	97.8% (135)	**0.031**
Fruit juice	73.2% (101)	82.0% (127)	**<0.0001**
Which fasting blood sugar level is normal in the morning? Less than 95 mg/dl	39.9% (55)	97.8% (135)	**<0.0001**
Which blood sugar level is normal 2 hours after eating? Less than 120 mg/dl	26.8% (37)	95.7% (132)	**<0.0001**
How can best be checked if your blood sugar levels are sufficiently under control? Based on a finger prick with a glucometer	80.1% (109)	98.5% (134)	**<0.0001**
What do you think about the treatment with insulin for GDM? This can lower the risk of an overweight baby	44.9% (61)	75.0% (102)	**<0.0001**
After delivery			
What do you think about breastfeeding after a pregnancy with GDM?			
This is good for the general health of the baby	58.7% (81)	89.9% (124)	**<0.0001**
This can lower the risk of diabetes and overweight in the baby later on	26.1% (36)	39.9% (55)	**0.002**
What do you think that happens with your GDM after your delivery? GDM disappears completely but I have a strongly increased risk of 50% to develop T2DM within 10 years	37.7% (52)	81.9% (113)	**<0.0001**

GDM: gestational diabetes mellitus; T2DM: type 2 diabetes mellitus
Only the correct answers are shown in this table. Differences are statistically significant if p <0.05 **(in bold)**.

Table 10: Comparison of the response rates on the knowledge questionnaire between group and individual education after the first education session

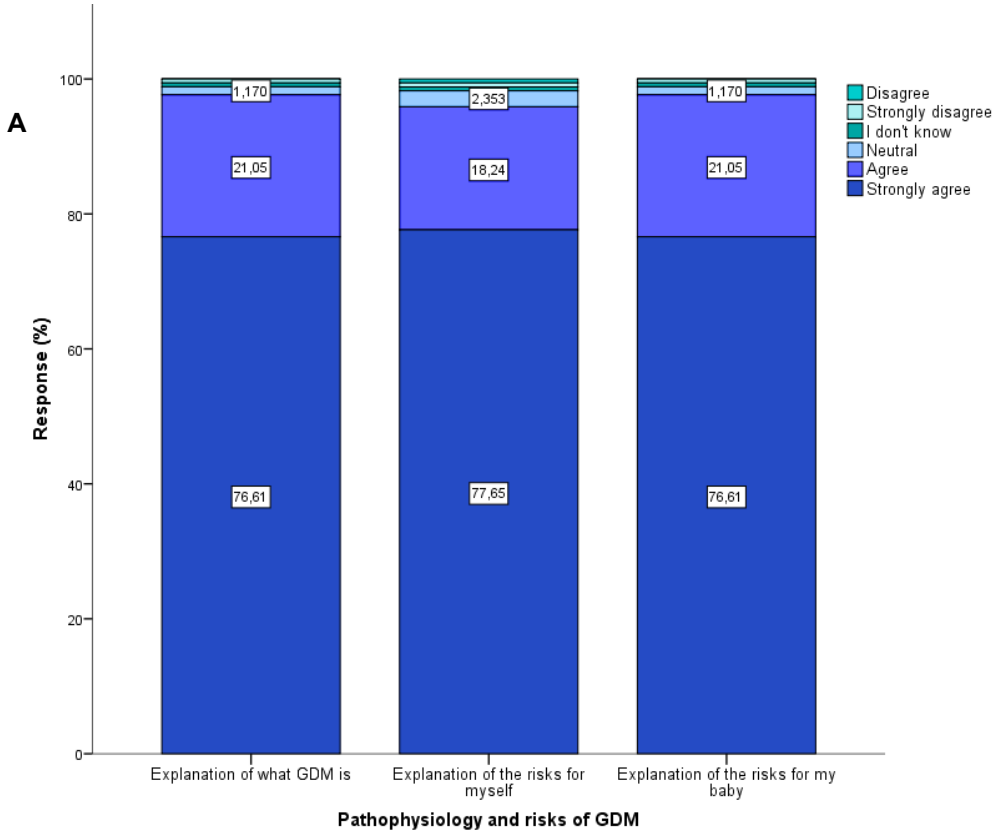
	Before 1st education (n=138)	After 2nd education (n=138)	P-value
Diagnosis of GDM			
When is GDM diagnosed? 24 – 28 weeks	98.8% (83)	98.9% (87)	1.000
How is GDM diagnosed? Based on a fasting blood collection in combination with drinking a sugar solution	88.1% (74)	89.8% (79)	0.914
Risk factors of GDM			
It's more likely to develop gestational diabetes if you:			
Are overweight before pregnancy	92.9% (78)	78.4% (69)	**0.013**
Gain too much weight during the pregnancy	39.3% (33)	39.8% (35)	1.000
Have had GDM during a previous pregnancy	73.8% (62)	67.0% (59)	0.421
Have a first degree relative (parents, brothers or sisters) with diabetes	88.1% (74)	73.9% (65)	**0.030**
Your age is > 30 years	59.5% (50)	52.3% (46)	0.422
Complications of GDM			
What are the consequences for the baby if the treatment of GDM is insufficient?			
Too high birth weight of the baby	95.2% (80)	95.5% (84)	1.000
Increased risk of diabetes for the baby later on	79.8% (67)	76.1% (67)	0.697
Increased risk of overweight for the baby later on	72.6% (61)	70.5% (62)	0.884
What are the risks for you if the treatment of GDM is insufficient?			
An increased risk for a difficult delivery	91.7% (77)	89.8% (79)	0.869
An increased risk for preeclampsia	91.7% (77)	83.0% (73)	0.138
An increased risk for a cesarean section	89.3% (75)	90.9% (80)	0.920
Treatment of GDM			
How is GDM initially treated after diagnosis?			
Dietary change and increasing physical activity	81.0% (68)	77.3% (68)	0.685
Insulin is only started if dietary change and physical activity is insufficient	75.0% (63)	59.1% (52)	**0.040**
Which food products do you have to restrict if you have GDM?			
Pie	96.4% (81)	90.9% (80)	0.243
Fruits	66.7% (56)	54.5% (48)	0.142
Sugared soda	97.6% (82)	94.3% (83)	0.478
Fruit juice	95.2% (80)	94.3% (83)	1.000
Which fasting blood sugar level is normal in the morning? Less than 95 mg/dl	98.8% (83)	92.0% (81)	0.081
Which blood sugar level is normal 2 hours after eating? Less than 120 mg/dl	97.6% (82)	92.0% (81)	0.194
How can best be checked if your blood sugar levels are sufficiently under control? Based on a finger prick with a glucometer	94.0% (79)	94.3% (83)	1.000
What do you think about the treatment with insulin for GDM? This can lower the risk of an overweight baby	77.4% (65)	72.7% (64)	0.597
After delivery			
What do you think about breastfeeding after a pregnancy with GDM?			
This is good for the general health of the baby	93.3% (70)	93.1% (82)	0.080
This can lower the risk of diabetes and overweight in the baby later on	36.9% (31)	34.5% (30)	0.864
What do you think that happens with your GDM after your delivery? GDM disappears completely but I have a strongly increased risk of 50% to develop T2DM within 10 years	83.3% (70)	85.2% (75)	0.895

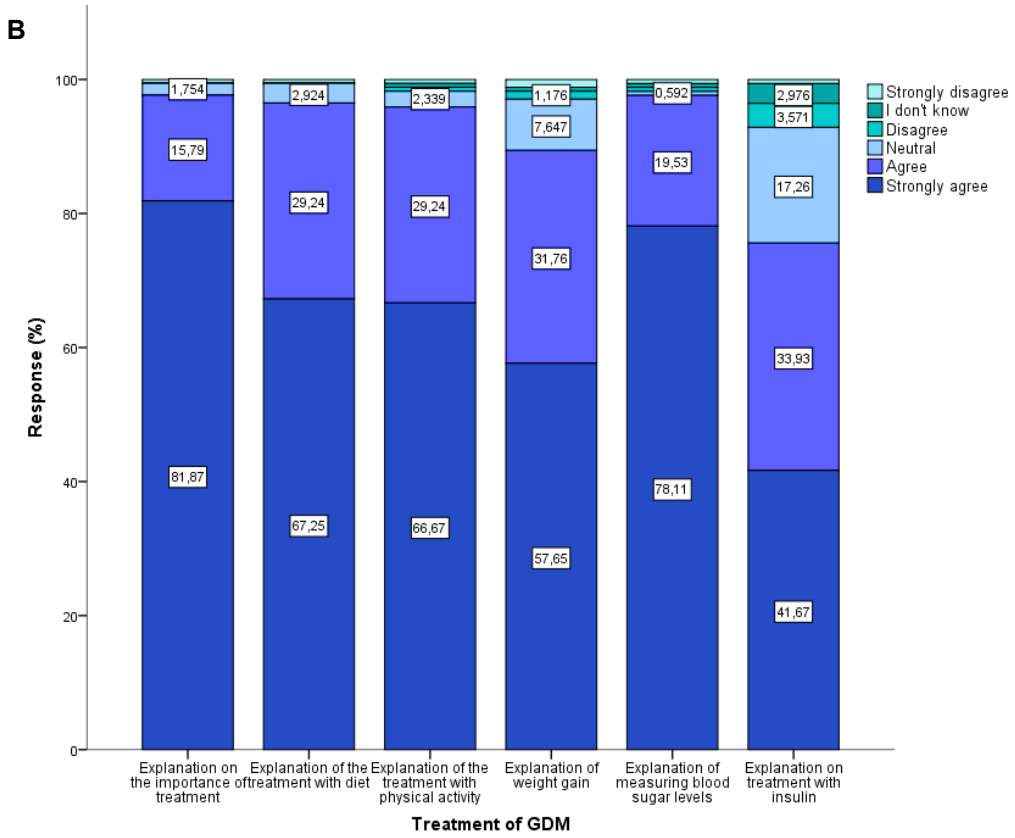
GDM: gestational diabetes mellitus; T2DM: type 2 diabetes mellitus
Only the correct answers are shown in this table. Differences are statistically significant if p <0.05 **(in bold)**.

4.6 Satisfaction about the education and treatment of GDM

4.6.1 SATISFACTION ABOUT THE CONTENT (N=171) AND DURATION (N=157) OF THE FIRST EDUCATION SESSION

Participants were asked to fill in a questionnaire to evaluate their satisfaction with twelve items that were discussed during the first education session, scoring each statement from ‘strongly disagreeing’ to ‘strongly agreeing’ or ‘not knowing’. Figure 4 (A-C) shows women’s satisfaction rates on these items categorized into ‘pathophysiology and risks of GDM’, ‘treatment of GDM’ and ‘follow-up and risks after delivery’. The participants were overall strongly satisfied with the education given about the pathophysiology and risks of GDM as shown in Figure 4A, with response rates reaching up to 77.0%. Satisfactions scores on items of the second category 'treatment of GDM' (Figure 4B) varied slightly more, but with the majority of the women still being strongly satisfied with the given explanation. Some items in this category such as ‘explanation of weight gain’ and ‘explanation on treatment with insulin’ showed lower satisfaction rates. 57.6% of all women fully agreed with the explanation on weight gain, 31.8% agreed and 7.6% were neutral. On the topic of treatment with insulin, only a minority (41.7%) fully agreed, 33.9% agreed, 17.3% were neutral and a small percentage (3.6%) disagreed that the information was clearly and relevant. On average, women were very satisfied with the explanation of the items in the last category ‘follow-up and risks after delivery’ (Figure 4C). Furthermore, almost all women (97.5%) were satisfied with the duration of the first session. Only 3 women (1.9%) indicated that the first session lasted too long and 1 woman (0.6%) had no opinion on this subject.





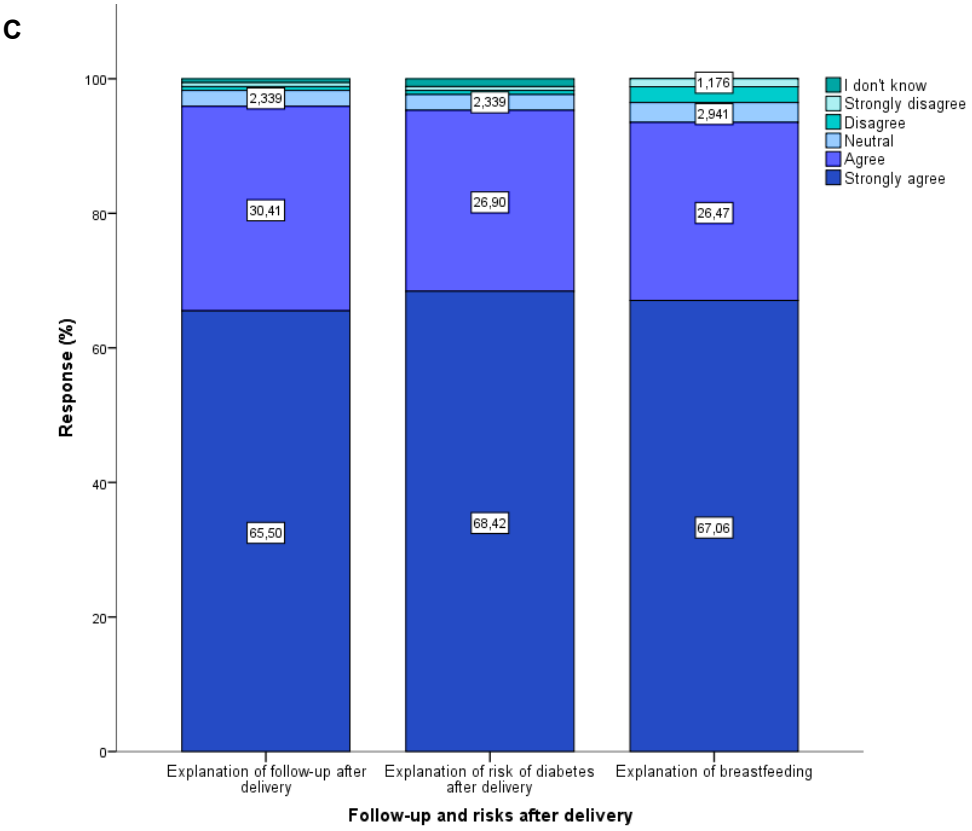


Figure 4 (A-C): bar charts of the response rates on the satisfaction items (questionnaire IIIa)

4.6.2 SATISFACTION ABOUT THE GROUP EDUCATION (N=84)

To evaluate the satisfaction of women diagnosed with GDM about group education, questions such as 'What did you think about the group education?', 'Which advantages or disadvantages does group education have compared to individual education?' and 'What do you think about the size of the group?' were asked after the first education session. In general, women were satisfied with the group education. 90.5% (75) of all women were pleased with the size of the group. Only 6.0% (5) found the group too small and 3.6% (3) had no opinion. A large majority of 77.4% (65) found that group education fulfilled their expectations, although 18 women (21.4%) indicated that they would prefer group education first and individual education afterwards. Only a small minority of 3 women (3.6%) preferred only individual education. The most frequently reported advantages of group education were 'learning from the questions of others' (77.4%) and 'learning from the experience of others' (52.4%), followed by 'feeling supported by the group' (23.8%) and 'helping you to stick to the advice' (15.5%). However, 7 women (8.3%) saw no advantages of group education and 3 women (3.6%) indicated that they felt inhibited by the group.

To determine whether women in group education were equally satisfied with the given explanation as women in individual education, satisfaction rates for all twelve items after the first education session were compared for both groups (Table 11). Women in both groups largely agreed or strongly agreed on all items. There were no significant differences between both groups, indicating that women receiving education in group are equally satisfied with the explanation as women who received the education individually.

Table 11: comparison of satisfaction rates of women in group education versus women in individual education (after the first education session)

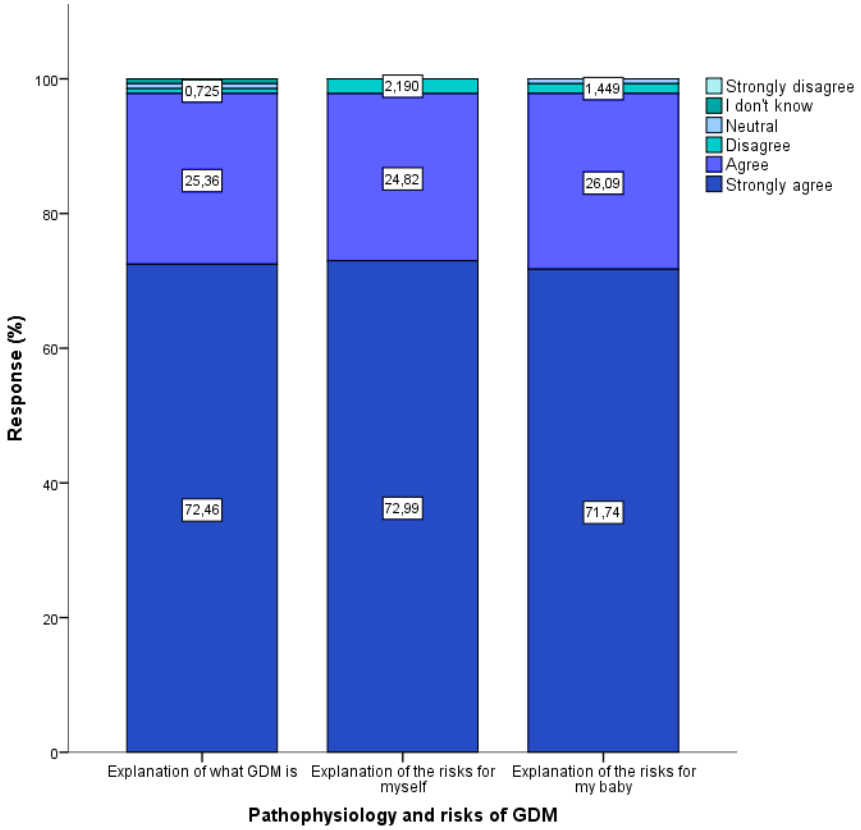
Items of explanation	P-value
What is GDM?	0.847
The importance of treatment	0.715
The risks for myself	0.594
The risks for my baby	0.875
Treatment with diet	0.277
Treatment with physical activity	0.964
Weight gain	0.757
Measuring of blood sugar levels	0.665
Treatment with insulin	0.382
Follow-up after delivery	0.800
Risk of diabetes after delivery	0.741
Breastfeeding	0.658

GDM: gestational diabetes mellitus.
Differences in satisfaction scores between group education and individual education are statistically significant if $p < 0.05$.

4.6.3 SATISFACTION ABOUT THE CONTENT (N=138) AND DURATION (N=104) OF THE SECOND EDUCATION SESSION

In general, a similar distribution was seen with regard to the satisfaction rates after the second education session (Figure 5 A-C). Concerning the pathophysiology and risks of GDM, about 72% of all women strongly agreed that the information was clear and relevant (Figure 5A). After the second education session, some topics related to the treatment such as 'explanation of weight gain' and 'explanation on treatment with insulin' scored less, with respectively 57.7% and 36.3% of all women 'strongly agreeing' with the information being clear and relevant (Figure 5B). Figure 5C illustrates that > 80% of all women agreed or strongly agreed with the explanation given about the follow-up and risks after delivery. However, these percentages were somewhat lower than after the first education (Figure 4C). When the participants were questioned about the duration of the second session, 89.4% of all respondents (93) were satisfied, whereas only 1 participant (1.0%) indicated that the second session lasted too long and 10 women (9.6%) had no opinion.

A



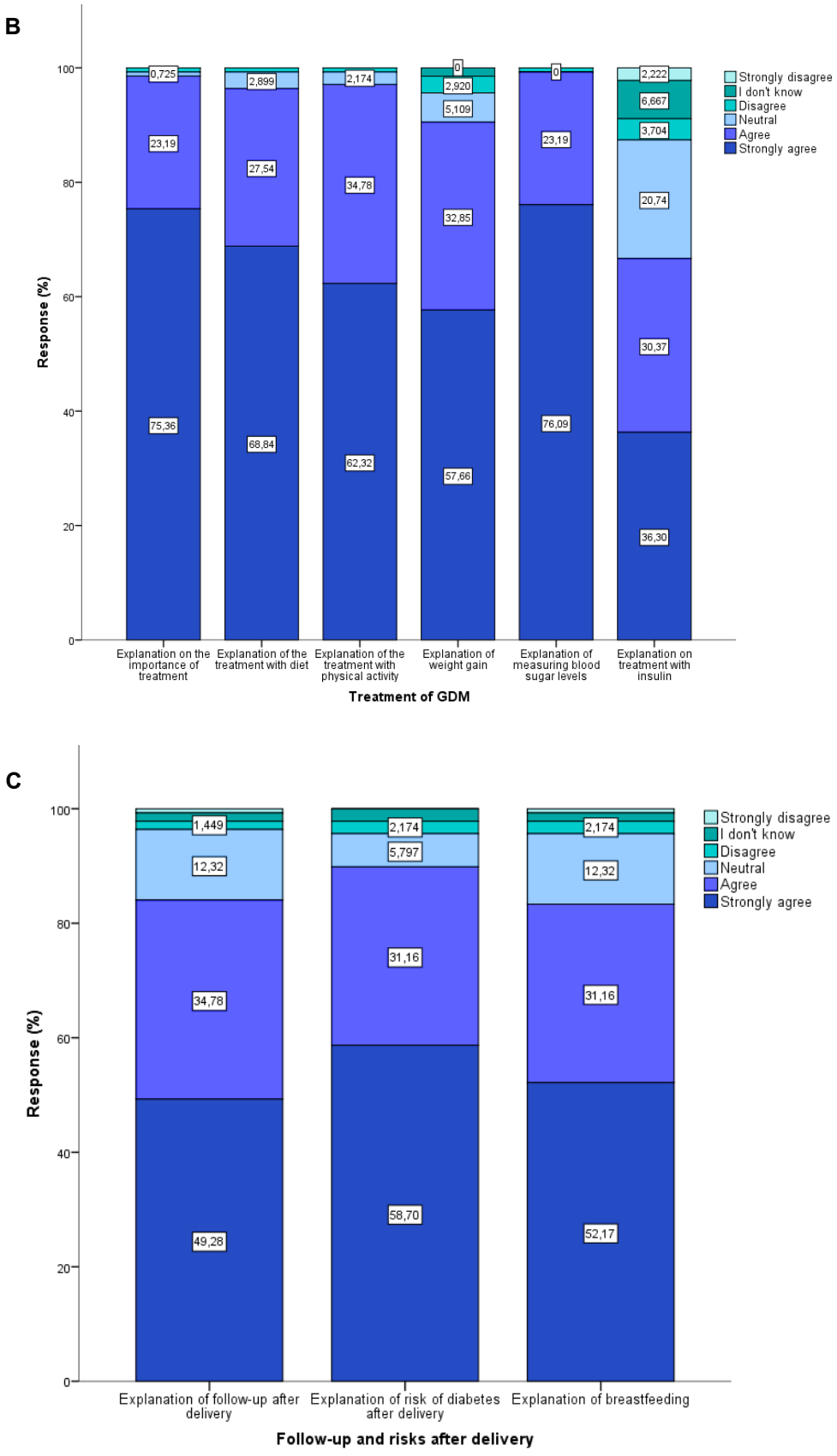
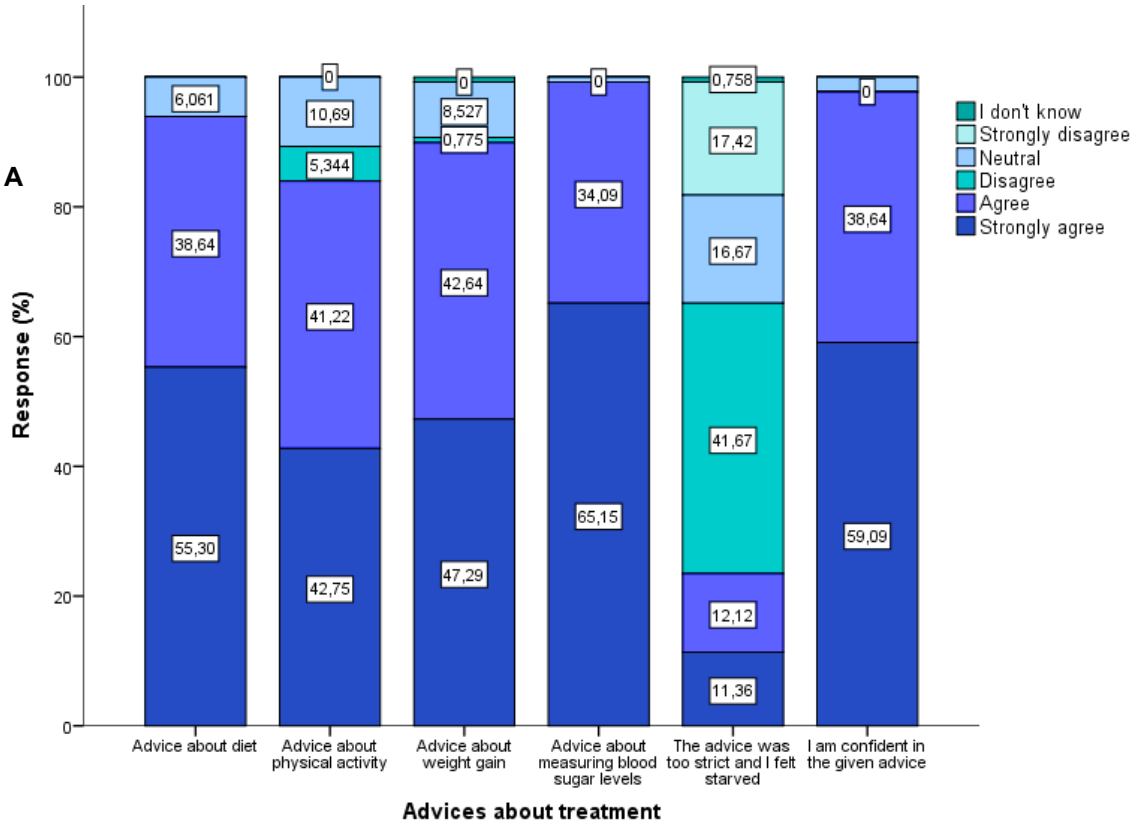


Figure 5 (A-C): bar charts of the response rates on the satisfaction items (questionnaire IIIb)

4.6.4 PATIENT SATISFACTION ABOUT THE MANAGEMENT (N=132) AND TREATMENT (N=126) OF GDM

After the second education session, women were also asked to evaluate the feasibility of the given advice for the management of GDM. Response rates on 7 items are presented in Figure 6 (A-B). A large majority of all women agreed or strongly agreed that is was possible to follow the advice about diet, physical activity, weight gain and glycemic measurements (Figure 6A). Almost all patients (97.7%) felt very confident in the given advice. 59.1% of respondents did not think the advice was too strict, although a considerable group (23.5%) perceived the advice to be too strict and indicated that they felt starved (Figure 6A). Of the 27 patients requiring insulin, only 12 completed the questionnaire after the second education session. Half of them agreed and 1 participant strongly agreed with the feasibility of the advice about the treatment with insulin, whereas 1 patient totally disagreed (Figure 6B).

Finally, patients were asked to fill in the DTSQ to assess satisfaction with their treatment regimen. A total of 126 participants completed this questionnaire. Mean total score for items 1, 4, 5, 6, 7 and 8 reached up to 27.6 (± 5.3) which reflects a high overall satisfaction with GDM treatment. Item 2 and 3 showed low scores (3.2 ± 2.2), indicating low rates of respectively perceived hyperglycemia and hypoglycemia. DTSQ scores were compared between group education (n=58) and individual education (n=68), the mean scores for item 1,4,5,6,7 and 8 were not significantly different (27.7 ± 5.3 vs. 27.4 ± 5.4, p=0.854). There were also no significant differences between both groups for items 2 and 3 (2.9 ± 1.9 vs. 3.5 ± 2.4, p=0.277).



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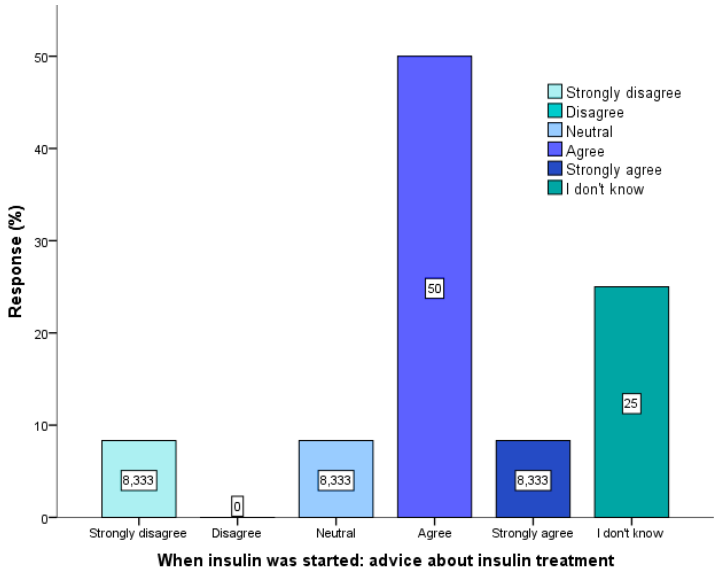

Figure 6 (A-B): bar charts of the response rates on the question 'Was it possible to follow the given advice?' (questionnaire IIIb)

4.7 Depression and anxiety

4.7.1 THE EMOTIONAL STATUS BEFORE THE FIRST AND AFTER THE SECOND EDUCATION SESSION

Outcomes of the CES-D (n=129) and STAI-6 (n=134) questionnaires were used to evaluate whether the diagnosis of GDM was associated with feelings of depression and anxiety and whether the education could have an impact on these feelings. Prior to the first education session, 35 women (27.1%) had a score ≥ 16 and were therefore clinically considered to be depressed. 26 of them (20.2%) were still depressed after the second education session, but the decrease in percentage was not statistically significant (p=0.124). Concerning the STAI-6 questionnaire, median total score decreased significantly from 12 (10 – 14) at the start of the first session to 11 (8 – 13) at the end of the second session (p<0.0001). When questioned about a treatment with insulin for GDM, 18.9% of all respondents indicated that they were afraid to inject themselves before the first education and 10.3% were afraid of hypoglycemia. These percentages even increased after the second education to 22.1% and 14% respectively, but this difference was not statistically significant (p=0.189 and p=0.092 respectively).

4.7.2 THE EMOTIONAL STATUS IN GROUP EDUCATION VERSUS INDIVIDUAL EDUCATION

In order to compare feelings of depression and anxiety between women receiving education in group and those receiving individual education, outcomes of the CES-D and STAI-6 tests were compared between both groups at the end of the first education session. 27.2% of all women receiving group education appeared to be depressed after their first education session, compared to 27.4% of all women following individual education (p=1.000). In terms of anxiety, median total score at the STAI-6 questionnaire was 12 (9 – 14) for women in group education and 11 (9 – 13) for those in the individual sessions, showing no significant difference as well (p=0.359).

4.8 Comments on the education sessions

After each session, patients had the opportunity to share comments about the education. Table 12 provides a summary of the most cited feedback, divided into group education and individual education. Most women indicated that the explanation was sufficient and felt that all of their questions had been answered during the education. However, topics such as follow-up after delivery and future risks should have been addressed in more detail according to a few patients. Another recurring comment was the demand for specific recipes and nutritional instructions. Women often indicated that they were well aware of what they should not eat, but were struggling with deciding what they were allowed to eat instead. In the meantime, recipes have been developed for different ethnicities to meet this demand and most patients were very pleased to receive them.

Table 12: feedback and remarks on the group and individual education sessions

	Feedback and remarks on the education	
Group education	Positive feedback	"Everything is clear" "You get to take home a lot of information as a reminder" "Thank you for the recipes and sport tips" "It feels good that we can always call or email with questions"
	Remarks	"Psychological aspect and perception may be addressed more" "More information about the follow-up and risks after delivery" "I am well aware of what I should not eat, but have a hard time deciding what I am allowed to eat instead"
Individual education	Positive feedback	"Everything was very clear for the time being" "The explanation is sufficient" "Good explanation, currently not the feeling that I'm missing information" "I personally enjoyed the feeling that there was taken a lot of time for me"
	Remarks	"More flexibility and positive coaching" "Risks for the baby after delivery should be discussed more" "More information on breastfeeding" "More specific nutritional instructions or recipes"

5. DISCUSSION

Due to the worldwide obesity epidemic and the adoption of the new 2013 WHO criteria, the prevalence of GDM will continue to increase. This leads to a number of practical challenges in the management of GDM, such as an increase in workload for health care providers and a growing demand for additional resources (36,37,41). In order to cope with this increasing burden, it may be useful to reconsider the way in which health care services are currently provided for women diagnosed with GDM (37). To this day, most women with GDM are treated in a one-to-one relationship with health care providers. However, group education could be a valuable alternative to partially offset the many practical problems associated with the increase in GDM prevalence. Gaining sufficient insight into the perceptions of patients with regard to their treatment is crucial to better organize educational programs adapted to the need of women with GDM. Therefore, this ongoing prospective study aims to evaluate treatment satisfaction of women with a recent diagnosis of GDM, receiving either group or individual education. In order to tailor the content of the education as much as possible to this particular population, additional information was collected with respect to the knowledge and awareness of women with GDM about their condition. Finally, information about feelings of anxiety and depression were evaluated to pay sufficient attention to psychological aspects associated with the diagnosis and treatment of GDM.

5.1 General characteristics

The general characteristics of this study cohort are largely consistent with previous publications of our research group (20,23,89,113). More than half of the subjects in our study were overweight (30.2%) or obese (27.9%) and 23.21% had an EM background. The vast majority of participants was highly educated and had a paid job. Of all women participating in our study, 18.4% needed insulin treatment during pregnancy, which is less compared with previous studies conducted in our center (20,113).

Pregnancy outcomes in our study such as cesarean section, macrosomia, LGA and LGA are comparable with those reported in previous research from our own study group (23) as well as from research investigating the effect of treatment of GDM on pregnancy outcomes (47). The percentage of caesarean sections seems to be higher in our study sample (30.9%) compared to the general pregnant population in Flanders (20.9%) based on the results of the 2016 annual report of the Flemish Centre for Study of Perinatal Epidemiology (SPE)(114). One might argue that this observation could logically be related to the more frequent occurrence of adverse neonatal outcomes such as fetal macrosomia and being LGA in babies born to women with GDM (15,18), making them more vulnerable to birth injuries such as shoulder dystocia and brachial plexus trauma (14). However, rates of macrosomia appeared to be lower in our study population (5.4%) compared to the general Flemish pregnant population (9.1%), suggesting that the recognition of GDM might have led to a lower threshold in making the decision of surgical delivery among women diagnosed with GDM (115). The increased medicalization requires sufficient attention in the treatment of women with GDM. Nevertheless, definitive conclusions cannot be drawn from this comparison, given the limited sample size in our study and thus a possible underreporting of rare pregnancy outcomes.

There was a high attendance rate (87.5%) at the three months postpartum 75g OGTT among our study participants. This is a very high percentage compared with other publications from our research group (23,89), which suggests that the strenuous efforts of our diabetes team to contact and stimulate all

patients several times to attend their appointment were successful. Eventually, 39.8% of all women who received the postpartum OGTT presented with glucose intolerance, which is in line with the findings of the retrospective analysis on glucose intolerance based on the 2013 WHO criteria in a two-step screening strategy with a GCT from our research group in UZ Leuven (23). This high percentage emphasizes the importance of timely detection and treatment of glucose intolerance in this high-risk population, especially since research has shown that both the implementation of intensive life style interventions and metformin therapy are capable of delaying or preventing diabetes in women with impaired glucose tolerance (IGT) and a history of GDM (87).

5.2 Evaluation of treatment satisfaction

Patient satisfaction is an important consideration in the organization of medical care, since improved satisfaction rates appear to be associated with a more effective engagement in health care programs (116). In this prospective study, patients were overall satisfied with the content and duration of both the first and second education session. The majority agreed with the clarity and relevance of the explanation that was given on the subject of twelve items categorized into themes such as pathophysiology, risks, treatment and follow-up of GDM. The topic 'treatment with insulin' scored less well, with only a minority fully agreeing with the clarity and relevance of the explanation on this matter. However, it was a carefully considered choice not to fully address this topic from the beginning of the treatment regimen, as only about 20% of all patients required treatment with insulin during pregnancy. It is therefore unnecessary to burden all women with this information right from the start, especially given the fact that nearly one fifth of all women with GDM reported that they were afraid to inject insulin.

Furthermore, a vast majority of participants (97.7%) were very confident in the given advice. Almost 60% of the patients indicated that they perceived the advice not to be too strict, although a considerable group of women (23.5%) still indicated that they felt starved. Women often indicated that they were well aware of what they should not eat, but had a hard time deciding what they were allowed to eat instead. The same observations were made in the Italian DAWN (Diabetes Attitudes, Wishes and Needs) Pregnancy Study, which was promoted by the IDF to evaluate the quality of life, wishes and needs in women diagnosed with GDM (117). In this study, a number of women indicated that they experienced difficulties in following the treatment regimen and that the dietary advice was one of their biggest concerns (117). The study also showed that the issue of eating habits among immigrant women with GDM is often even more difficult compared with indigenous women (117). To address these concerns, which have been observed among participants in the ELENA study as well, recipes have been developed by our study group in cooperation with specialized diabetes dietitians that contain concrete guidelines and adapted recipes for Flemish, Asian and North-African cuisine.

The results of the DTSQ revealed that our study cohort was overall very satisfied with the treatment regimen. Regarding the same subject, a Malaysian study explored the association of attitude and treatment satisfaction with glycemic level among women with GDM and suggested that a higher treatment satisfaction is associated with better glycemic control and a higher educational level (97). Other studies in the field of diabetes research demonstrated that treatment satisfaction of patients with diabetes can have a significant impact on clinical outcomes as well as on treatment adherence (96,118). Therefore, determining patient satisfaction levels with their GDM treatment could be a useful tool in improving healthcare for this particular population.

5.3 Evaluation of group education

Group education is an efficient and cost-effective alternative to individual education in the organization of diabetes care (91), but there is a paucity of research on this subject in the field of GDM. In our study, 90% of all participants receiving group education were satisfied with the group size and almost 80% indicated that the group education fulfilled their expectations. Nevertheless, a small minority (3.6%) reported that they felt inhibited by the group and that they preferred individual education over group education. This is in contrast to a study from New Zealand, evaluating patient satisfaction with current antenatal diabetes care, which showed that only a minority of the questioned subjects would consider attending a group session, fearing that less attention could be paid to the individual needs of each patient (98). This may also be one of the reasons why a small number of patients in our study would rather receive only individual education.

The most important advantages associated with group education appeared to be learning from others' questions and experiences. This is in line with another observational study on this subject, which contributed the beneficial effects of their group prenatal care program to factors associated with group education such as learning from the experience of peers, a greater connection with health care providers and a motivating group dynamic (93). Other potential benefits of group education could be improved glycemic control and higher patient satisfaction scores (94). On the contrary, the present study was not able to determine a significant difference in satisfaction rates on the twelve items and in DTSQ scores between patients receiving group education and those receiving individual education. This discrepancy could partially be explained by the fact that the abovementioned study (94) compared group education with standard prenatal care instead of individual education, and was therefore more powered to find a difference in satisfaction rates. Additional high-quality studies in this research area could be useful to determine the cost-effectiveness, feasibility and possible benefits of group education compared with the conventional individual education.

5.4 Evaluation of knowledge about GDM

In our study, we aimed to evaluate the knowledge of women with a recent diagnosis of GDM about their condition and the impact of education on their understanding of GDM. We also compared the knowledge of women in group education with those in individual education to determine whether the type of education could have exerted an influence on the degree of knowledge that women developed.

5.4.1 KNOWLEDGE ABOUT GDM BEFORE THE FIRST AND AFTER THE SECOND EDUCATION SESSION

Knowledge of participants about the questioned aspects of GDM was significantly higher for almost all domains after the first education. Therefore, it could be suggested that education of women diagnosed with GDM had a beneficial impact on the understanding of their condition, which is in line with the findings of a recent study assessing the effectiveness of group education on knowledge of women with newly diagnosed GDM (95). This is an important finding, given that improved knowledge about GDM might result in better adoption of a healthy lifestyle, better treatment adherence and better self-management.

Women displayed an overall good knowledge about GDM diagnosis and some obvious risk factors such as overweight before pregnancy, history of GDM and family history of diabetes prior to education. Other risk factors such as higher age and excessive weight gain during pregnancy were less well known. Women in pregnancy might make the mistaken assumption that they have to 'eat for two', which could explain why this risk factor was not recognized as such by the majority. Furthermore, patients in this study had a good understanding of the management of GDM and more specifically of which foods should be restricted in most cases, but failed to recognize ‘fruits’ as a restricted food category. Evidence in literature contains discrepancies regarding this subject, since patients with GDM showed highest knowledge about diet and food values in one study (99), whereas another study assessing the knowledge of pregnant women about GDM established that only a minority knew which foods were permitted to eat (119). A possible explanation for this difference could be that women in the latter study were questioned even before they were screened for GDM and therefore had no knowledge at all on the subject compared with women who are already diagnosed with GDM.

Knowledge about blood sugar levels was inadequate at baseline, but improved significantly after the second education. This might be a logical observation as this was new information to most participants in the study. With the exception of preeclampsia, most women had a good insight in the perinatal risks associated with the occurrence of GDM.

Long-term complications of GDM both for mother and child were poorly understood prior to education, but this knowledge increased significantly after the second education session. According to a study assessing risk perception for diabetes among women with a history of GDM, the majority of the participants recognized that GDM was a risk factor for future diabetes, but less than one-fifth actually believed themselves to be at high risk for diabetes (120). This is an important consideration, because GDM might be the best well-known predictor for the subsequent development of T2DM (2) and underestimation of risk is known to act as an obstacle to adopt a healthy lifestyle after pregnancy (120). Therefore, it remains of great importance to educate women about the long-term risks of GDM but also to ensure that as many women as possible are followed up properly after their pregnancy (25).

5.4.2 KNOWLEDGE ABOUT GDM IN GROUP EDUCATION VERSUS INDIVIDUAL EDUCATION

There is a paucity of studies comparing knowledge of women in group education with individual education in the treatment of GDM. Despite the fact that a recent study was able to demonstrate the beneficial impact of group education sessions on women’s knowledge of GDM, it made no comparison with individual education (95). Women in our study showed an overall good knowledge about GDM in group education as well as in individual education. Only a few significant differences were discovered in the understanding of GDM between both groups. For example, risk factors were more often recognized by women in group education. Women receiving group education were also more often aware of the fact that insulin is only started if dietary change and physical activity is insufficient compared with women in individual education. Individual sessions were always offered in Dutch, English or French, but for some women none of these three was their native language. This might partially explain the fact that these women understood certain aspects less well than women in group education, all of whom were Dutch-speaking. As suggested in the literature, ethnicity, educational status and language proficiency are related to health literacy (100) and women from non-Caucasian backgrounds need greater resources to better understand their condition (7). Women with a low educational level, from an EM background or non-Dutch speaking women diagnosed with GDM might therefore benefit from individual education in order to improve treatment adherence.

5.5 Evaluation of depression and anxiety

Our study aimed to evaluate whether the diagnosis of GDM was associated with feelings of depression and anxiety and whether these feelings could be mediated through education. Depression is a relatively common condition in women with GDM (101,102) and can lead to poor management, thus increasing the risk of adverse pregnancy outcomes (103). In our study, 27.1% of all women were considered clinically depressed prior to the first education. It is important for health care providers to be aware of the risk of antenatal depression when treating women with GDM and to pay sufficient attention to these feelings throughout their pregnancy. To our knowledge, few studies have examined the effect of education on the emotional status of women with GDM. A trial evaluating the effect of treatment of GDM on pregnancy outcomes, revealed a reduction in the incidence of depression three months postpartum in the intervention group compared with routine care (47). In our study, 20.2% of all women remained depressed after the second education session, although this decrease in percentage was not significant. Improvement of feelings of depression may be attributed to the reassuring, empathetic approach of the specialized healthcare providers, which are an important source of information for women with a recent diagnosis of GDM. Furthermore, women with GDM appear to have an elevated risk of postpartum depression as well, which may interfere with lifestyle change efforts in the postpartum period (104,121). Health care providers should therefore recognize the postpartum period among these high-risk individuals as an important time window of opportunity for the well-being of both women and offspring by encouraging preventive lifestyle measures as much as possible.

In addition to feelings of depression, the diagnosis of GDM can also cause maternal anxiety and stress related to the perception of a high-risk pregnancy, the fear of maternal and neonatal complications and the feeling of losing control during the process of dietary management (104). However, feelings of anxiety tend to decrease throughout pregnancy, which could be related to the understanding that GDM is a self-limiting condition and which might suggest that education and reassurance by health care providers is successful in dissipating anxiety in women diagnosed with GDM (105). A systematic review analyzing the impact of GDM and its symptoms on quality of life (QOL), found that QOL was significantly worse in women with GDM in both the short and long-term, but that it could be improved by attending an educational program (122). This is in line with the findings in our study population, where feelings of anxiety were apparent prior to the first education, but declined significantly after education was given. Moreover, insulin use could be an additional source of anxiety and stress, with women on insulin experiencing higher levels of perceived stress related to failure of dietary management and difficulties in achieving glycemic targets (76,104). In our study, 18.9% of all women confirmed to be afraid of injecting themselves with insulin. In order not to frighten these women, we decided to discuss this topic only briefly during the first education and to give a more extensive education at the time that treatment with insulin is needed.

To our knowledge, no studies have been conducted to compare feelings of depression and anxiety between women with GDM in group versus individual education. Even in the field of normal prenatal care there is very little evidence to be found on this subject. A prospective cohort study compared the effects of group prenatal care with individual prenatal care on psychosocial outcomes and found that women with inadequate social support or high pregnancy-related distress might experience greater benefits from group prenatal care (123). In our study, no significant differences in terms of feelings of depression and anxiety could be found between patients receiving group education and those receiving individual education. Further research will be required to confirm whether group education can achieve results that are comparable with individual education.

5.6 Strengths, limitations and future perspectives

A strength of this study was the use of structured questionnaires to evaluate knowledge, satisfaction and emotional status of women with GDM before and after the education sessions. The inclusion of women who followed individual education made it possible to compare the outcomes of women in group education with women in individual education. However, the distribution of participants in both groups did not occur in a randomized manner so we were not able to account for selection bias in this study. Women following individual education were more often non-Dutch speaking with an EM background and we can therefore not exclude that this inequality has exerted an effect on the outcomes of this study. Another limitation of our study is the fact that no long-term follow-up data were collected. Studies evaluating the long-term effects on psychosocial outcomes in women with GDM would be useful to complement this lack of information. Since this is an ongoing study, definite conclusions will only be made when the proposed number of 200 participating women is reached.

6. CONCLUSION

The first results of the ongoing ELENA study suggest that (group) education is well perceived by women with a recent diagnosis of GDM. Women were generally satisfied with their treatment and their knowledge about GDM improved considerably after the education. These are important observations, since improved patient satisfaction appears to be associated with a more effective engagement in health care programs. A good understanding of the disease might result in improved treatment adherence and self-management.

The ELENA study also showed that the diagnosis of GDM may be accompanied by feelings of anxiety and depression, but that these feelings may decrease after education about GDM is given by a specialized diabetes educator and dietitian.

In addition, group education appears to be a valuable alternative to individual education, as no important differences could be demonstrated between women in group education and individual education in terms of their knowledge about GDM, their satisfaction with the education and their emotional status. These results are encouraging, since the implementation of group education can have an important added value in anticipating the increasing prevalence of GDM. Additional information about the perceptions of women diagnosed with GDM on (group) education is useful to further optimize the content and delivery of the education sessions in the future.

7. NEDERLANDSTALIGE SAMENVATTING

7.1 Inleidend literatuuroverzicht

Zwangerschapsdiabetes (ZWDM) is een frequente medische complicatie tijdens de zwangerschap en wordt gedefinieerd als 'elke vorm van glucose-intolerantie die optreedt of vastgesteld wordt tijdens de zwangerschap' (4). De wereldwijde prevalentie van ZWDM varieert tussen de 3 en 14% van alle zwangerschappen, afhankelijk van de populatie, screeningsstrategie en diagnostische criteria (4). Traditionele risicofactoren voor ZWDM zijn een toegenomen maternale leeftijd, overgewicht en obesitas, etniciteit, familiale belasting en een voorgeschiedenis van ZWDM (5–8). Een gezonde levensstijl kan daarentegen juist bescherming bieden tegen de ontwikkeling van ZWDM (8,9).

Tijdens een zwangerschap produceert de placenta verscheidene hormonale factoren ter promotie van de foetale ontwikkeling. Deze hormonen interfereren in het tweede en derde trimester van de zwangerschap echter met de signalering van insulinereceptoren, waardoor een afname van insulinegevoeligheid in de perifere weefsels wordt geïnitieerd (11). In een normale zwangerschap reageren de bètacellen van de maternale pancreas hierop met een verhoging van de insulinesecretie. ZWDM treedt op wanneer de capaciteit van de bètacellen wordt overtroffen en het lichaam niet in staat is om de insulineproductie te verhogen in verhouding tot de mate van insulineresistentie (12). Glucose kan bijgevolg onvoldoende in de perifere weefsels worden opgenomen en stapelt op in het bloed (13). Vanaf het tweede trimester van de zwangerschap reageert de foetale pancreas op deze maternale hyperglycemie door insuline af te scheiden, wat foetale hyperinsulinemie veroorzaakt (14). De combinatie van maternale en foetale hyperglycemie enerzijds, en foetale hyperinsulinemie anderzijds, verhoogt het risico op ongunstige zwangerschapsuitkomsten zoals pre-eclampsie, vroeggeboorte en macrosomie (14–17) . Er is een verhoogd risico op complicaties tijdens en vlak na de bevalling zoals een verhoogd voorkomen van keizersneden, schouderdystocie en neonatale hypoglycemie (14,16,19). Daarnaast hebben vrouwen met ZWDM op lange termijn een verhoogde kans op het ontwikkelen van type 2 diabetes mellitus (T2DM) (22) en ook hun nakomelingen zijn vatbaarder voor de ontwikkeling van obesitas, het metabool syndroom en T2DM (26–29). De behandeling van vrouwen met ZWDM resulteert echter in een vermindering van perinatale complicaties (47–50). In eerste instantie bestaat deze behandeling uit educatie, aanpassing van de voeding, matige lichaamsbeweging en glucosemonitoring (51). Als levensstijlmaatregelen onvoldoende blijken om de glycemische doelen te bereiken, moet farmacologische therapie worden toegevoegd (38).

Tot op heden is er geen uniforme consensus omtrent de screeningsstrategie en diagnostische criteria voor ZWDM. In 2010 werden nieuwe diagnostische criteria voorgesteld door de International Association of Diabetes and Pregnancy Study Group (IADPSG) op basis van het risico op de ontwikkeling van ongunstige zwangerschapsuitkomsten (35). Deze consensusverklaring beveelt een universele één-staps screeningsstrategie aan, met een 2-uur durende 75 g OGTT, uitgevoerd tussen 24 en 28 weken zwangerschap. De aanbevolen afkapwaarden zijn hierbij nuchter ≥ 92 mg/dl, na 1 uur ≥ 180 mg/dl en na 2uur ≥ 153 mg/dl (35). Bovendien is één abnormale glucosewaarde voldoende voor de diagnose van ZWDM. Er blijft echter heel wat controverse bestaan met betrekking tot de IADPSG-aanbevelingen, aangezien dit zal leiden tot een aanzienlijke toename van het aantal vrouwen met ZWDM, waardoor de werkdruk en geassocieerde kosten zullen toenemen (37). Studies die één-staps versus twee-staps benaderingen vergelijken, waren tot op heden inconsistent (38). Om verschillende screeningsstrategieën voor ZWDM te evalueren op basis van de IADPSG-criteria, werd een grote

Belgische prospectieve multicentrische cohort studie, de 'Belgian Diabetes in Pregnancy study' (BEDIP-N studie), gestart in 2014 (45). De eerste resultaten laten zien dat de afkapwaarde voor de GCT moet worden verlaagd tot ≤ 130 mg/dl indien een twee-staps screeningsstrategie wordt gebruikt in combinatie met een GCT, om een sensitiviteit van minstens 70% te behalen (46). In afwachting van een nieuwe Vlaamse consensus, maakt het UZ Leuven momenteel gebruik van de IADPSG-criteria in combinatie met een twee-staps screeningsstrategie, waarbij een OGTT alleen wordt uitgevoerd als de GCT abnormaal is (met een afkapwaarde van ≥ 140 mg/dl).

De behandeling van ZWDM is een arbeidsintensieve discipline, waarbij een multidisciplinair team van endocrinologen, verloskundigen, vroedvrouwen, diabeteseducatoren en diëtisten ingeschakeld wordt (37). De continue toename in de prevalentie van ZWDM vormt een uitdaging voor zorgverleners om hoogwaardige zorg te kunnen blijven voorzien (37). De organisatie van groepseducatie zou een waardevolle oplossing kunnen zijn om met deze toenemende werkdruk om te gaan. Daarom bestaat de algemene doelstelling van de ELENA-studie uit het evalueren van de tevredenheid van vrouwen met ZWDM over de (groeps)educatie en de behandeling. Ook wordt gepeild naar de kennis van vrouwen met ZWDM over hun aandoening en wordt onderzocht of de diagnose van ZWDM gepaard gaat met gevoelens van depressie en angst.

7.2 Materiaal en methoden

De ELENA-studie is een mono-centrische, prospectieve en observationele cohort studie, uitgevoerd in het Universitair Ziekenhuis Gasthuisberg te Leuven. Sinds oktober 2015 wordt de eerste individuele educatiesessie in de behandeling van ZWDM zo veel mogelijk vervangen door een gestructureerde groepseducatie. Deze groepssessie wordt gegeven door een gespecialiseerde diabeteseducator en diëtiste en bestaat uit maximum 6 deelnemers. Voor anderstalige vrouwen of vrouwen die de groepssessie niet kunnen bijwonen, gebeurt de eerste educatiesessie individueel. De eerste educatiesessie wordt steeds gegeven aan de hand van een gestructureerde PowerPoint presentatie, die ontwikkeld is in overleg met diabeteseducatoren, diëtisten en een endocrinoloog gespecialiseerd in ZWDM. Een Frans- en Engelstalige vertaling van de presentatie is voorzien voor anderstalige patiënten. Tijdens deze sessie worden de pathofysiologie, risicofactoren, diagnose en gevolgen van ZWDM besproken, alsook de verschillende aspecten van de behandeling, waaronder gewichtscontrole, gezonde voeding, lichaamsbeweging en zelfmonitoring van de bloedglucose. Tot slot wordt er meer informatie gegeven over de follow-up na de zwangerschap, de risico's van ZWDM op lange termijn en de voordelen van borstvoeding. Binnen één tot twee weken na de eerste sessie wordt voor alle patiënten een individuele follow-up sessie bij de diëtiste voorzien. Tijdens deze consultatie worden de eetgewoonten en glycemiewaarden van de patiënt overlopen en wordt de therapie op punt gesteld.

De ELENA-studie startte in oktober 2015 en heeft als vooropgesteld doel om 200 vrouwen met ZWDM te rekruteren over een periode van vier jaar. Vrouwen worden uitgenodigd om deel te nemen aan de studie na hun diagnose van ZWDM op basis van de 2 uur durende 75g OGTT met gebruik van de IADPSG-criteria. De behandeling en opvolging van de deelnemers verschilt daarbij op geen enkele manier van de normale zorg voor vrouwen met ZWDM. Verschillende vragenlijsten worden door de vrouwen ingevuld aan het begin van de eerste educatiesessie en telkens na de eerste en tweede educatiesessie. Een zelfontworpen vragenlijst wordt gebruikt om algemene socio-demografische informatie te verzamelen, zoals opleidingsniveau, etniciteit en financiële en burgerlijke staat. Kennis van de vrouwen over ZWDM wordt geëvalueerd aan de hand van een zelfontworpen vragenlijst met 14

meerkeuzevragen. Daarnaast werden vragenlijsten ontwikkeld om de tevredenheid over de (groeps)educatie te beoordelen aan de hand van vragen op basis van een Likertschaal en meerkeuzevragen. Ook wordt er gebruik gemaakt van de volgende gevalideerde vragenlijsten om respectievelijk de tevredenheid van de patiënten over hun behandeling, gevoelens van depressie en gevoelens van angst te evalueren: de 'Diabetes Treatment Satisfaction Questionnaire – status version' (DTSQs), de 'Center for Epidemiologic Studies Depression' (CES-D) vragenlijst en de verkorte 'Spielberger State-Trait Anxiety Inventory' (STAI-6) vragenlijst. Tot slot worden een aantal algemene klinische gegevens van de vrouwen verzameld uit het medisch elektronisch dossier, alsook data over de diagnose, de behandeling en over maternale en neonatale zwangerschapsuitkomsten.

7.3 Resultaten en discussie

Tot op heden namen 175 vrouwen deel aan de ELENA-studie, waarvan 86 deelnemers hun eerste educatiesessie in groep kregen. Over de gehele periode werden 37 groepssessies gegeven met een gemiddelde van 3 deelnemers per groep. De gemiddelde leeftijd van alle vrouwen was 32,5 jaar. Respectievelijk 30.2% en 27.9% van de deelnemers had overgewicht en obesitas. Van alle vrouwen had 12.5% een voorgeschiedenis van ZWDM en 19.1% had een eerstegraads familielid met T2DM. Een minderheid van de deelnemers (23.1%) was van niet-Westerse origine en de meerderheid (70.9%) was hoog opgeleid. Van alle vrouwen met ZWDM had 18.4% een behandeling met insuline nodig. 10.7% had zwangerschapshypertensie, 6.7% had pre-eclampsie en 30.9% beviel door middel van een keizersnede. Schouderdystocie, macrosomie, LGA en SGA waren aanwezig in respectievelijk 2%, 5.4%, 10.9% en 10.2% van alle baby's. Na de bevalling kregen alle deelnemers een afspraak voor een postpartum screening door middel van een 2 uur durende 75g orale glucosetolerantietest (OGTT), waarvan 87.5% deze test effectief heeft laten uitvoeren. 39.8% van alle vrouwen die de postpartum OGTT kregen, vertoonde glucose-intolerantie. Dit hoge aantal benadrukt het belang van een tijdige detectie en behandeling van glucose-intolerantie in deze populatie, vooral omdat uit onderzoek is gebleken dat zowel levensstijlinterventies als metformine de onset van T2DM kunnen vertragen of voorkomen bij vrouwen met een verminderde glucosetolerantie na ZWDM (87).

Deelnemers gaven aan dat zorgverleners zoals diabeteseducatoren (63.4%), gynaecologen (58.9%) en diëtisten (56%) de belangrijkste bronnen zijn voor informatie omtrent ZWDM. Uit de kennisvragenlijsten kon worden afgeleid dat de vrouwen in het algemeen over een goede kennis beschikten wat betreft de meeste thema's rond ZWDM. Sommige aspecten waren bij aanvang van de educatie minder goed gekend, zoals de opvolging van de glycemiewaarden (26,8%) en het feit dat de consumptie van fruit beperkt moest worden (18.8%). Deze kennis verbeterde echter significant na de tweede educatiesessie (respectievelijk 95.7% en 55.1%). Langdurige complicaties van ZWDM, zowel voor moeder als kind, waren slecht begrepen voorafgaand aan de educatie, maar ook deze kennis nam significant toe na de tweede educatiesessie. Dit is in overeenstemming met de bevindingen uit een studie die de perceptie van het risico op diabetes beoordeelde bij vrouwen met een voorgeschiedenis van ZWDM. De meerderheid van de vrouwen in dit onderzoek erkende dat ZWDM een risicofactor is voor diabetes, maar minder dan een vijfde geloofde dat zij zelf een hoog risico op diabetes liepen (120).

De patiënten waren in het algemeen tevreden over de inhoud en duur van zowel de eerste als de tweede educatiesessie. De meerderheid was het eens met de duidelijkheid en relevantie van de uitleg die gegeven werd rond de verschillende aspecten van ZWDM. Het onderwerp 'behandeling met insuline' scoorde minder goed, met slechts een minderheid van de patiënten (41.7%) die volledig akkoord ging

met de gegeven uitleg. Een volledige educatie omtrent insulinegebruik werd echter enkel voorzien voor patiënten waarbij een insulinebehandeling gestart werd. Verder hadden bijna alle deelnemers (97.7%) veel vertrouwen in het gegeven advies. Toch gaf een aanzienlijke groep vrouwen (23.5%) aan dat ze de adviezen te streng vonden en dat ze zich uitgehongerd voelden. Overeenkomstig met deze bevinding gaven een aantal vrouwen uit de Italiaanse DAWN studie aan dat zij problemen ondervonden bij het volgen van hun behandelingsregime en dat het voedingsadvies één van hun grootste zorgen was (117). Om tegemoet te komen aan deze zorgen, ontwikkelde onze studiegroep recepten in samenwerking met gespecialiseerde diëtisten als leidraad voor vrouwen met ZWDM. Tot slot onthulden de resultaten van de DTSQ vragenlijst dat onze deelnemers over het algemeen zeer tevreden waren met hun behandeling. Een Maleisische studie bij vrouwen met ZWDM toonde in dit verband aan dat een hogere behandeltevredenheid geassocieerd is met een betere glycemische controle (97). Andere studies hebben gedemonstreerd dat de behandeltevredenheid van diabetespatiënten een significant effect kan hebben op klinische uitkomsten en op therapietrouw (96,118).

Deelnemers aan de groepssessie waren in het algemeen zeer tevreden over de gegeven educatie. 90% van alle deelnemers in groep was tevreden met de groepsgrootte en bijna 80% gaf aan dat het groepsonderwijs aan hun verwachtingen voldeed. Niettemin meldde een kleine minderheid (3.6%) dat ze zich geremd voelden door de groep en dat ze de voorkeur gaven aan individuele educatie. Dit is in tegenstelling tot de bevindingen van een onderzoek uit Nieuw-Zeeland, waaruit bleek dat slechts een minderheid van de ondervraagde personen zou overwegen om deel te nemen aan een groepssessie, uit vrees dat er minder aandacht zou besteed worden aan de individuele behoeften van elke patiënt (98). Er was overigens geen significant verschil in tevredenheid over de educatie en behandeling tussen patiënten die groepseducatie kregen en patiënten die individuele educatie kregen.

Resultaten van de CES-D en STAI-6 vragenlijsten werden gebruikt om te evalueren of de diagnose van ZWDM geassocieerd was met symptomen van depressie en angst en of de educatie een invloed had op deze gevoelens. Voorafgaand aan de eerste sessie had 27.1% van de deelnemers een score ≥ 16 op de CES-D vragenlijst en werd daarom klinisch depressief beschouwd. Dit aantal nam af tot 20.2% na de tweede sessie, maar deze vermindering was niet statistisch significant ($p = 0.124$). De literatuur toont aan dat depressie een relatief vaak voorkomende aandoening is bij vrouwen met ZWDM (101,102) en dat dit kan leiden tot slecht zelfmanagement, waardoor het risico op ongunstige zwangerschapsuitkomsten toeneemt (103). Het is belangrijk dat zorgverleners zich bewust zijn van het verhoogd risico op antenatale depressie bij vrouwen met ZWDM en voldoende aandacht besteden aan depressieve symptomen tijdens het verloop van hun zwangerschap. Wat de STAI-6 vragenlijst over angst betreft, daalde de mediane totaalscore wel significant van 12 aan het begin van de eerste sessie tot 11 aan het einde van de tweede sessie ($p < 0,0001$). Een systematische review over de impact van ZWDM op levenskwaliteit toonde, overeenkomstig met onze bevindingen, aan dat vrouwen met ZWDM een verminderde levenskwaliteit hebben op zowel korte als lange termijn, maar dat dit verbeterd kan worden door het volgen van een educatief programma (122). Tot slot konden in onze studie geen significante verschillen in gevoelens van depressie en angst worden gevonden tussen patiënten die groepslessen volgden en vrouwen die individuele educatie kregen.

7.4 Conclusie

De eerste resultaten van de ELENA-studie tonen aan dat de (groeps)educatie als positief wordt ervaren door vrouwen met een recente diagnose van ZWDM. Patiënten waren over het algemeen zeer tevreden met hun behandeling en hun kennis over ZWDM verbeterde aanzienlijk na de educatie. Dit zijn belangrijke bevindingen, omdat een goede patiënttevredenheid in de literatuur geassocieerd wordt met een betere betrokkenheid bij zorgprogramma's en omdat een goed begrip van de ziekte kan leiden tot een betere therapietrouw en zelfmanagement. Deze studie toont ook aan dat de diagnose van ZWDM gepaard kan gaan met gevoelens van angst en depressie, maar dat deze gevoelens kunnen afnemen na voldoende educatie over ZWDM.

Daarenboven blijkt groepseducatie een waardevol alternatief te zijn voor individuele educatie, aangezien de overgrote meerderheid van de deelnemers aangeeft dat de groepseducatie aan hun verwachtingen voldoet. Er werden verder geen significante verschillen gevonden tussen vrouwen in groepseducatie en individuele educatie in termen van hun kennis over ZWDM, hun tevredenheid over de educatie en behandeling, en hun emotionele status. Deze resultaten zijn bemoedigend, omdat de implementatie van groepseducatie een belangrijke toegevoegde waarde kan hebben in de anticipatie op de toenemende prevalentie van ZWDM. Aanvullende informatie omtrent de ervaringen van vrouwen met ZWDM over de (groeps)educatie is nuttig om de educatieve sessies in de toekomst verder te optimaliseren.

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APPENDIX 1: GENERAL QUESTIONNAIRE (I)

1. **Welk is het hoogste diploma of de hoogste graad die u behaald heeft, hoger onderwijs buiten beschouwing gelaten?**

□ lager onderwijs

□ lager secundair onderwijs-kunst

□ lager secundair onderwijs-algemeen

□ lager secundair onderwijs-technisch

□ lager secundair onderwijs-beroeps

□ hoger secundair onderwijs-kunst

□ hoger secundair onderwijs-algemeen

□ hoger secundair onderwijs-technisch

□ hoger secundair onderwijs-beroeps

□ nog op school

□ geen diploma

□ ander diploma: welk? …

2. **Welk is het hoogste diploma van hoger onderwijs dat u behaald hebt?**

□ hoger onderwijs buiten de universiteit, korte type of bachelor

□ hoger onderwijs buiten de universiteit, lange type of master

□ universiteit

□ nog op hogeschool of universiteit

□ geen diploma hoger onderwijs

□ ander diploma hoger onderwijs: welk? …

3. **Wat is uw origine?**

□ Blank □ Noord-Afrikaans □ Turks □ Zwart Afrikaans □ Latijns-Amerikaans
□ Midden-Oosten □ Aziatisch □ Andere…

4. **Heeft u momenteel een betaalde job?** □ ja □ nee

5. **Wat is uw burgerlijke staat?**

□ gehuwd en samenwonend met echtgeno(o)te

□ (wettelijk) samenwonend

□ gehuwd en gescheiden levend van echtgeno(o)te

□ nooit gehuwd

□ gescheiden

□ weduwe

APPENDIX 2: QUESTIONNAIRE ON KNOWLEDGE OF GDM (II)

1. **Waar haalt u of verwacht u informatie rond zwangerschapsdiabetes te bekomen? (Meerdere antwoorden zijn mogelijk)**
   - □ gynaecoloog
   - □ vroedvrouw
   - □ diabeteseducator
   - □ diëtiste
   - □ diabetesarts
   - □ huisarts
   - □ internet: welke website: …..
   - □ informatiebrochure
   - □ familie
   - □ vrienden
   - □ andere bron: welke: …
   - □ ik weet het niet

2. **Je hebt meer kans op het ontwikkelen van zwangerschapsdiabetes als je: (Meerdere antwoorden zijn mogelijk.)**
   - □ overgewicht hebt vóór de zwangerschap
   - □ te weinig bijkomt tijdens de zwangerschap
   - □ teveel bijkomt tijdens de zwangerschap
   - □ zwangerschapsdiabetes hebt gehad tijdens een vorige zwangerschap
   - □ een eerstegraads familielid (ouders, broers of zussen) hebt met suikerziekte
   - □ je leeftijd < 30 jaar is
   - □ je leeftijd > 30 jaar is
   - □ ik weet het niet

3. **Wanneer wordt meestal de diagnose gesteld van zwangerschapsdiabetes? (1 antwoord mogelijk)**
   - □ op 12-16 weken
   - □ op 8-22 weken
   - □ op 24-28 weken
   - □ na 32 weken
   - □ bij de bevalling
   - □ ik weet het niet

4. **Hoe wordt de diagnose van zwangerschapsdiabetes gesteld? (1 antwoord mogelijk)**
   - □ op basis van urine
   - □ via een gewone bloedname
   - □ via een niet-nuchtere bloedname in combinatie met het drinken van een suikeroplossing
   - □ via een nuchtere bloedname in combinatie met het drinken van een suikeroplossing
   - □ ik weet het niet

5. **Hoe wordt zwangerschapsdiabetes in eerste instantie behandeld na het vaststellen ervan? (Meerdere antwoorden zijn mogelijk.)**
   - □ aanpassing van voeding
   - □ opdrijven van fysieke activiteit
   - □ aanpassing van voeding en opdrijven van fysieke activiteit
   - □ insuline wordt pas gestart wanneer de aanpassing van voeding en fysieke activiteit onvoldoende effect hebben
   - □ insuline wordt direct gestart
   - □ pillen voor de suikerziekte worden direct gestart
   - □ ik weet het niet

6. **Wat dien je zeker te beperken in de voeding als je zwangerschapsdiabetes hebt? (Meerdere antwoorden zijn mogelijk.**
   - □ bruin brood
   - □ taart
   - □ fruit
   - □ volkoren pasta
   - □ gesuikerde frisdrank
   - □ fruitsap
   - □ ik weet het niet

7. **Wat is een goede nuchtere suikerwaarde in het bloed?(1 antwoord mogelijk)**
   - □ minder dan 120
   - □ minder dan 110
   - □ minder dan 100
   - □ minder dan 95
   - □ minder dan 80
   - □ ik weet het niet

8. **Wat is een goede suikerwaarde in het bloed 2 uur na het eten? (1 antwoord mogelijk)**
   - □ minder dan 200
   - □ minder dan 140
   - □ minder dan 120
   - □ minder dan 100
   - □ minder dan 80
   - □ ik weet het niet

9. **Hoe kan het beste gecontroleerd worden of je suikerwaarden voldoende onder controle zijn? (1 antwoord mogelijk)**
   - □ via de urine
   - □ via een bloedname
   - □ via vingerprikken met een glucometer
   - □ er is geen controle nodig
   - □ ik weet het niet

10. **Wat denkt u over behandeling met insuline voor zwangerschapsdiabetes? (Meerdere antwoorden zijn mogelijk.)**
    - □ Dit kan schadelijk zijn voor de baby
    - □ Dit kan het risico op een te zware baby verminderen.

□ Ik ben bang om te spuiten.
□ Ik zal hierdoor meer bijkomen in gewicht.
□ Ik zal hierdoor afvallen in gewicht.
□ Ik ben bang dat hierdoor de suiker vaak te laag gaat komen.
□ Ik ben bang dat hierdoor de suiker vaak te hoog zal komen.
□ Ik weet het niet

11. Bij onvoldoende behandeling van de zwangerschapsdiabetes, kan dit bij de baby leiden tot? (Meerdere antwoorden zijn mogelijk.)

□ geboorteafwijkingen bij de baby
□ te laag gewicht van de baby
□ geen invloed op het gewicht van de baby
□ te hoog gewicht van de baby
□ verhoogt het risico op suikerziekte later bij de baby
□ verhoogt het risico op overgewicht later bij de baby
□ Ik weet het niet

12. Bij onvoldoende behandeling van zwangerschapsdiabetes, kan dit bij u leiden tot? (Meerdere antwoorden zijn mogelijk.)

□ geen verhoogd risico op problemen bij de bevalling
□ moeilijkere bevalling
□ meer kans op zwangerschapsvergiftiging
□ meer kans op een keizersnede
□ ik weet het niet

13. Wat denkt u over borstvoeding na een zwangerschap met zwangerschapsdiabetes? (Meerdere antwoorden zijn mogelijk.)

□ via de moedermelk kan suikerziekte worden doorgegeven
□ dit is goed voor de algemene gezondheid van de baby
□ dit is niet goed voor de algemene gezondheid van de baby
□ dit kan het risico op suikerziekte en overgewicht bij de baby later verminderen
□ ik weet het niet

14. Wat denkt u over uw risico na de bevalling op suikerziekte? (1 antwoord mogelijk)

□ Zwangerschapsdiabetes verdwijnt niet volledig na de bevalling en ik zal daarom blijvend suikerziekte hebben
□ Zwangerschapsdiabetes verdwijnt volledig na de bevalling en ik heb hierdoor geen risico meer om later blijvend suikerziekte te ontwikkelen
□ Zwangerschapsdiabetes verdwijnt volledig na de bevalling maar ik blijf een klein risico hebben van 10% om binnen de 10 jaar een blijvende vorm van suikerziekte te ontwikkelen
□ Zwangerschapsdiabetes verdwijnt volledig na de bevalling maar ik blijf een matig verhoogd risico hebben van 20% om binnen de 10 jaar een blijvende vorm van suikerziekte te ontwikkelen
□ Zwangerschapsdiabetes verdwijnt volledig na de bevalling maar ik blijf een sterk verhoogd risico hebben van 50% om binnen de 10 jaar een blijvende vorm van suikerziekte te ontwikkelen.
□ Ik weet het niet

APPENDIX 3: QUESTIONNAIRE ON THE SATISFACTION OF THE FIRST EDUCATION SESSION (IIIA)

1. De informatie over de volgende onderwerpen was duidelijk en relevant voor mij?

Zet achter elke uitspraak een kruisje onder wat het beste uw gevoel weergeeft.

	Helemaal niet akkoord	**niet akkoord**	**neutraal**	**akkoord**	**Volledig akkoord**	**Ik weet het niet**
Uitleg rond wat zwangerschaps-diabetes is						
Uitleg rond waarom behandeling belangrijk is						
Uitleg rond de risico's voor mezelf						
Uitleg rond de risico's voor mijn baby						
Uitleg rond behandeling met dieet						
Uitleg rond fysieke activiteit						
Uitleg rond gewichtstoename						
Uitleg rond het meten van de suikerwaarden						
Uitleg rond behandeling met insuline						
Uitleg rond de opvolging na de bevalling						
uitleg over risico op diabetes na de bevalling						
uitleg over borstvoeding na een zwangerschap met suikerziekte						

2. **Indien u uitleg kreeg in groep: Wat vond je van de uitleg in groep? (Meerdere antwoorden zijn mogelijk.)**

   □ Ik zou liever enkel individuele uitleg krijgen.
   □ Ik zou liever uitleg in groep krijgen en nadien ook nog individueel.
   □ De uitleg in groep voldoet aan mijn verwachtingen.
   □ Ik weet het niet.

3. **Welke voor- of nadelen heeft uitleg in groep volgens u in vergelijking met individuele uitleg? (Meerdere antwoorden zijn mogelijk.)**

   □ U leert uit de vragen van anderen.
   □ U leert uit de ervaringen van anderen.
   □ U voelt zich gesteund door de groep.
   □ Het helpt om zelf beter de adviezen te volgen.
   □ U ziet geen voordelen.
   □ U voelt zich geremd door de groep.
   □ Ik weet het niet.

4. **Indien u uitleg kreeg in groep: Wat vindt u van de grootte van de groep?**
   □ De groep is in aantal goed.
   □ De groep is in aantal te klein
   □ De groep is in aantal te groot.
   □ Ik weet het niet

5. **Wat vindt u van de duur van de eerste sessie? (bij de diabeteseducator)**

   □ De duur is goed.
   □ Het duurt te lang.
   □ Het duurt te kort.
   □ Ik weet het niet.

6. **Wat vindt u van de duur van de 2de sessie? (bij de diëtiste)**

   □ De duur is goed.
   □ Het duurt te lang.
   □ Het duurt te kort.
   □ Ik weet het niet.

7. **Wat zou volgens u nog meer of duidelijker aan bod moeten komen?**
   ……

APPENDIX 4: QUESTIONNAIRE ON THE SATISFACTION OF THE SECOND EDUCATION SESSION (IIIB)

1. De informatie over de volgende onderwerpen was duidelijk en relevant voor mij?

Zet achter elke uitspraak een kruisje onder wat het beste uw gevoel weergeeft.

	Helemaal niet akkoord	**niet akkoord**	**neutraal**	**akkoord**	**Volledig akkoord**	**ik weet het niet**
Uitleg rond wat zwangerschaps-diabetes is						
Uitleg rond waarom behandeling belangrijk is						
Uitleg rond de risico's voor mezelf						
Uitleg rond de risico's voor mijn baby						
Uitleg rond behandeling met dieet						
Uitleg rond fysieke activiteit						
Uitleg rond gewichtstoename						
Uitleg rond het meten van de suikerwaarden						
Uitleg rond behandeling met insuline						
Uitleg rond de opvolging na de bevalling						
uitleg over risico op diabetes na de bevalling						
uitleg over borstvoeding na een zwangerschap met suikerziekte						

2. Kon u de adviezen die werden gegeven goed opvolgen?

Zet achter elke uitspraak een kruisje onder wat het beste uw gevoel weergeeft.

	Helemaal niet akkoord	niet akkoord	neutraal	akkoord	volledig akkoord	ik weet het niet
Rond voeding						
Rond fysieke activiteit						
Indien insuline werd gestart: rond de behandeling met insuline						
Rond de gewichtstoename						
Rond het meten van de suikerwaarden						
De adviezen zijn te streng en u voelt zich uitgehongerd						
U heeft vertrouwen in de adviezen die u werd gegeven						

3. Indien u uitleg kreeg in groep: Wat vond je van de uitleg in groep? (Meerdere antwoorden zijn mogelijk.)

□ Ik zou liever enkel individuele uitleg krijgen.
□ Ik zou liever uitleg in groep krijgen en nadien ook nog individueel.
□ De uitleg in groep voldoet aan mijn verwachtingen.
□ Ik weet het niet.

4. Welke voor- of nadelen heeft uitleg in groep volgens u in vergelijking met individuele uitleg? (Meerdere antwoorden zijn mogelijk.)

□ U leert uit de vragen van anderen.
□ U leert uit de ervaringen van anderen.
□ U voelt zich gesteund door de groep.
□ Het helpt om zelf beter de adviezen te volgen.
□ U ziet geen voordelen.
□ U voelt zich geremd door de groep.
□ Ik weet het niet.

5. Indien u uitleg kreeg in groep: Wat vindt u van de grootte van de groep?

□ De groep is in aantal goed.
□ De groep is in aantal te klein
□ De groep is in aantal te groot.
□ Ik weet het niet

6. Wat vindt u van de duur van de eerste sessie? (bij de diabeteseducator)

□ De duur is goed.
□ Het duurt te lang.
□ Het duurt te kort.
□ Ik weet het niet.

7. Wat vindt u van de duur van de 2de sessie? (bij de diëtiste)

□ De duur is goed.
□ Het duurt te lang.
□ Het duurt te kort.
□ Ik weet het niet.

8. Wat zou volgens u nog meer of duidelijker aan bod moeten komen?

……

APPENDIX 5: CES-D QUESTIONNAIRE ON DEPRESSION (IV)

Omcirkel achter elke uitspraak het cijfer dat het beste uw gevoel of gedrag van de afgelopen week weergeeft.

Tijdens de afgelopen week	Zelden of nooit (<1dag)	Soms of weinig (1-2 dagen)	Regelmatig (3-4 dagen)	Meestal of altijd (5-7 dagen)
1. Stoorde ik me aan dingen die me gewoonlijk niet storen.	0	1	2	3
2. Had ik geen zin in eten, was mijn eetlust slecht.	0	1	2	3
3. Bleef ik maar in de put zitten, zelfs als familie of vrienden probeerden me eruit te halen.	0	1	2	3
4. Voelde ik me even veel waard als ieder ander	3	2	1	0
5. Had ik moeite mijn gedachten bij mijn bezigheden te houden.	0	1	2	3
6. Voelde ik me gedeprimeerd.	0	1	2	3
7. Had ik het gevoel dat alles wat ik deed me moeite koste.	0	1	2	3
8. Had ik goede hoop voor de Toekomst.	3	2	1	0
9. Vond ik mijn leven een Mislukking.	0	1	2	3
10. Voelde ik me bang.	0	1	2	3
11. Sliep ik onrustig.	0	1	2	3

Tijdens de afgelopen week	Zelden of nooit (<1dag)	Soms of weinig (1-2 dagen)	Regelmatig (3-4 dagen)	Meestal of altijd (5-7 dagen)
12. Was ik gelukkig.	3	2	1	0
13. Praatte ik minder dan Gewoonlijk.	0	1	2	3
14. Voelde ik me eenzaam.	0	1	2	3
15. Waren de mensen onaardig.	0	1	2	3
16. Had ik plezier in het leven.	3	2	1	0
17. Had ik huilbuien.	0	1	2	3
18. Was ik treurig.	0	1	2	3
19.Had ik het gevoel dat mensen me niet aardig vonden.	0	1	2	3
20. Kon ik maar niet op gang komen.	0	1	2	3

APPENDIX 6 : STAI QUESTIONNAIRE ON ANXIETY (V)

Zet achter elke uitspraak een kruisje onder wat het beste uw gevoel weergeeft.

	Geheel niet	**Een beetje**	**Tamelijk veel**	**Zeer veel**
Ik voel me kalm.	4	3	2	1
Ik ben gespannen.	1	2	3	4
Ik voel me onrustig.	1	2	3	4
Ik ben ontspannen.	4	3	2	1
Ik voel me tevreden.	4	3	2	1
Ik maak me zorgen.	1	2	3	4

APPENDIX 7 : DTSQS QUESTIONNAIRE ON TREATMENT SATISFACTION (VI)

De volgende vragen gaan over de behandeling van uw suikerziekte (met insuline, tabletten en/of dieet) en over uw ervaring gedurende de afgelopen weken. Beantwoord elke vraag door op elke schaal een cijfer te omcirkelen.

1. Hoe tevreden bent u met uw huidige behandeling?

zeer tevreden	6	5	4	3	2	1	0	zeer ontevreden

2. Hoe vaak heeft u de laatste tijd ondervonden dat uw bloedsuikerwaarden te hoog waren?

zeer vaak	6	5	4	3	2	1	0	helemaal niet

3. Hoe vaak heeft u de laatste tijd ondervonden dat uw bloedsuikerwaarden te laag waren?

zeer vaak	6	5	4	3	2	1	0	helemaal niet

4. Hoe gemakkelijk/handig vindt u uw behandeling de laatste tijd?

zeer gemakkelijk / zeer handig	6	5	4	3	2	1	0	zeer ongemakkelijk / zeer onhandig

5. Hoe flexibel vindt u uw behandeling de laatste tijd?

zeer flexibel	6	5	4	3	2	1	0	zeer inflexibel

6. Hoe tevreden bent u over hetgeen u van uw suikerziekte begrijpt?

zeer tevreden	6	5	4	3	2	1	0	zeer ontevreden

7. Zou u deze vorm van behandeling aanbevelen aan iemand anders met uw vorm van suikerziekte?

ja, ik zou de behandeling zeker aanbevelen	6	5	4	3	2	1	0	nee, ik zou de behandeling zeker niet aanbevelen

8. Hoe tevreden zou u zijn om uw huidige behandelingsvorm voort te zetten?

zeer tevreden	6	5	4	3	2	1	0	zeer ontevreden

Wilt u a.u.b. nakijken of u bij alle vragen één cijfer omcirkeld hebt.