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ABSTRACT

Objective To study how lifestyle coaching with motivational interviewing to improve adherence to healthy eating affects gestational weight gain and fetal growth in pregnant women with type 2 diabetes in a real-world setting.

Research design and methods A cohort study including a prospective intervention cohort of consecutive, singleton pregnant, Danish-speaking women with type 2 diabetes included between August 2015 and February 2018 and a historical reference cohort included between February 2013 and August 2015. The intervention consisted of a motivational interviewing to improve adherence to healthy eating in addition to routine care. The reference cohort received routine care only. The main outcomes were gestational weight gain and large for gestational age (LGA) infants.

Results Ninety-seven women were included in the intervention cohort and 92 in the reference cohort. Pre-pregnancy body mass index (32.8±6.9 kg/m^2 vs 32.4±7.4 kg/m^2, p=0.70), gestational weight gain (9.2±5.8 kg vs 10.2±5.8 kg, p=0.25), HbA1c in early pregnancy (6.7%±1.1% vs 6.5%±1.3% (50±12 mmol/mol vs 48±14 mmol/mol), p=0.32) and late pregnancy (5.9%±0.5% vs 6.0%±0.6% (41±6 mmol/mol vs 42±7 mmol/mol), p=0.34) were comparable in the two cohorts. LGA infants occurred in 20% vs 31%, p=0.07, respectively, and after adjustment for maternal characteristics 14% vs 27% delivered LGA infants (p=0.04). Birth weight z-score was 0.24±1.36 vs 0.61±1.38, p=0.06.

Conclusions Motivational interviewing to improve adherence to healthy eating in addition to routine care in pregnant women with type 2 diabetes tended to reduce fetal overgrowth without major effect on gestational weight gain. Further studies investigating the cost-benefit of enhancing motivation are needed.

Trial registration number NCT02883127.

Significance of this study

What is already known about this subject?

- Poor maternal glycemic control and excessive gestational weight gain contribute to fetal overgrowth that is prevalent in pregnant women with type 2 diabetes.
- Motivational interviewing is effective in promoting adherence to diet programs and reducing body weight in non-pregnant patients with type 2 diabetes.

What are the new findings?

- Motivational interviewing to improve adherence to healthy eating in pregnant women with type 2 diabetes tended to reduce fetal overgrowth without major effect on gestational weight gain.

How might these results change the focus of research or clinical practice?

- Focus on motivation in clinical practice may improve pregnancy outcome in pregnant women with type 2 diabetes.
- Further studies investigating the cost-benefit of enhancing motivation in pregnant women with diabetes are needed.

INTRODUCTION

The prevalence of type 2 diabetes in pregnancy is increasing,[1] mainly due to decreased age of onset of type 2 diabetes.[2]

Fetal overgrowth is a major complication in women with type 2 diabetes and the prevalence of large for gestational age (LGA) infants is 23%–35%.[3–5] Fetal overgrowth is associated with both maternal and neonatal complications, for example, shoulder dystocia, cesarean section and neonatal hypoglycemia[6 7] and long-term offspring risk of obesity and diabetes.[8]

Excessive gestational weight gain contributes to fetal overgrowth in healthy women[9 10] and in women with diabetes independent of glycemic control and pre-pregnancy body mass index (BMI).[5 11 12] However, obtaining appropriate gestational weight gain is challenging, especially in obese women,[13] leading to a high prevalence of excessive gestational weight gain in women with type 2 diabetes.[5 13–15] Lifestyle intervention including diet, exercise or both combined during pregnancy in healthy women reduces the risk of excessive gestational weight gain on average by 20%.[16]

Motivational interviewing that focuses on enhancing the women's own motivation for lifestyle changes[17] is effective in promoting adherence to diet and exercise programs[18] and reducing body weight in non-pregnant patients with type 2 diabetes.[19] During pregnancy, the Vitamin D and Lifestyle Intervention for GDM Prevention (DALI) study used motivational interviewing as an intervention in overweight and obese pregnant women.[20] The intervention that included both diet and physical activity reduced gestational weight gain by 2.3 kg compared with the control group.

Lifestyle intervention studies enhancing motivation in pregnant women with type 2 diabetes are lacking.

The aim of the present study was to investigate how lifestyle coaching with motivational interviewing to improve adherence to healthy eating affects gestational weight gain and fetal growth in pregnant women with type 2 diabetes in a real-world setting.

RESEARCH DESIGN AND METHODS

Study design

A cohort study consisting of a prospective intervention cohort and a historical reference cohort in a real-world setting. The intervention consisted of a motivational interviewing to improve adherence to healthy eating in addition to routine care and was offered to all pregnant women with type 2 diabetes. The reference cohort received routine care only. The goals for glycemic control and gestational weight gain were the same in the two cohorts as was the routine obstetrical control and management. The focus of the motivational interviewing was to encourage the women to follow the recommended diabetes diet[21] and to comply to local gestational weight gain recommendations.[22] Gestational weight gain (kg) and LGA infants (birth weight >90th percentile) were the main outcomes.

Study population

All consecutive women with type 2 diabetes from a geographically well-defined region of approximately 4 million inhabitants were invited to participate from August 2015 to February 2018. The inclusion criteria were: singleton pregnancy before 20 weeks in women aged ≥18 years. All women were followed at either Center for Pregnant Women with Diabetes, Rigshospitalet or Department of Obstetrics and Endocrinology, Odense University Hospital. The women were registered as having type 2 diabetes, if the diagnosis was present at referral. Women diagnosed with type 2 diabetes in early pregnancy with HbA1c ≥6.5% (48 mmol/mol) were also included (the intervention cohort: n=4 and the reference cohort: n=3). Exclusion criteria were very few: previous bariatric surgery (n=3) and for ethical reasons, insufficient Danish language skills (n=40).

The reference cohort consisted of all pregnant women with type 2 diabetes treated at the centers in the period February 2013 to August 2015 and matched the same inclusion and exclusion criteria as the intervention cohort. If a woman had more than one pregnancy in the study period, the pregnancy in which she underwent intervention was the pregnancy included (n=9). Data for the reference cohort were registered prospectively but collected retrospectively.

The lifestyle intervention with motivational interviewing

All women received individual one-to-one sessions with a lifestyle coach at each pregnancy visit at the centers, preferably every 2 weeks. The lifestyle coaching was based on principles of patient empowerment and cognitive behavioral techniques, inspired by motivational interviewing.[17] An individual action plan for improving dietary behavior was made during the first session and evaluated and tailored in subsequent sessions. At each visit the following dietary objectives were presented for the patient, of which one was to be achieved or maintained until the next session: (1) watch portion size—focus on the amount of carbohydrates in each meal; (2) eat mainly carbohydrates of low glycemic index (for example, more vegetables or whole grain products); (3) reduce the intake of carbohydrate of high glycemic index (for example, less or no takeaway food, less or no cakes, candy, snacks, chips, ice cream, sugary beverage). Furthermore, the women were motivated to watch daily weight changes.

The lifestyle coaches were midwives, who had received special training in the motivational interviewing with focus on lifestyle changes as a part of the DALI study.[20] During the DALI study, the midwives had regular assessment of their skills in the use of the motivational interviewing and had years of practical experience. The first session of the motivational interviewing lasted 45 min. To minimize the time consumption for the patients and the caregivers, the sessions of motivational interviewing were thereafter sought combined with routine diabetes care within the time frame of one appointment, if possible. Women living a long distance from the clinic could convert a minor part of the one-to-one contacts to telephone calls with the lifestyle coaches.

Women in the intervention cohort were judged to be compliant to the intervention, if attending at least 80% of the visits.

The routine diabetes care for both cohorts

At the first pregnancy visit, the women received a one-to-one consultation with a nurse, a registered dietitian and a diabetologist. Thereafter, the women were seen by a diabetes caregiver preferably every 2 weeks throughout pregnancy.

The women received information from a dietitian about the recommended diabetes diet[21] and education in carbohydrate exchange including an introduction to a local smartphone application with pictures and information on the carbohydrate amounts to aid learning. The goals were: (1) adequate nutrient intake to support a healthy pregnancy; (2) carbohydrates mainly deriving from low glycemic index sources; and (3) a total daily

energy intake of approximately 1673 kcal (7000 kJ) including 175 g carbohydrates in total (43 E%) with approximately 150 g deriving from the major carbohydrate sources (bread, potatoes, rice, pasta, fruits, and dairy products).

The women were encouraged to be physically active for at least 30 min/day if this was not medically contraindicated.

The goals for gestational weight gain followed the Copenhagen guidelines[22] for pregnant women with diabetes according to pre-pregnancy BMI, that is, pre-pregnancy BMI<25 kg/m^2: aiming for 100 g/week in the first half of pregnancy and thereafter 400 g/week with a total weight gain of 10–15 kg. BMI 25–29.9 kg/m^2: aiming for 100 g/week in the first half of pregnancy and thereafter 300 g/week, with a total weight gain of 5–8 kg. BMI≥30 kg/m^2: aiming for 0 g/week in the first half of pregnancy and thereafter 200 g/week, with a total weight gain of 0–5 kg.

Self-monitored plasma glucose measurements were recommended seven times daily, aiming for preprandial plasma glucose values between 4 and 6 mmol/L and 90 min postprandial values between 4 and 8 mmol/L. The aim for HbA1c was <6.7% (50 mmol/mol) in the first half of pregnancy and <5.8% (40 mmol/mol) in the second half of pregnancy.

Before pregnancy most women were treated with diet alone or in a combination with oral antidiabetic drugs and/or glucagon-like peptide-1 (GLP-1) analogs. At first pregnancy visit, the treatment with oral antidiabetic drugs and/or GLP-1 analogs was discontinued and not used during pregnancy. Therefore, insulin treatment was often initiated or tailored.

At each pregnancy visit, HbA1c and weight were measured, and a dipstick of sterile urine was screened for proteinuria and ketonuria. The daily insulin dose, the occurrence of mild hypoglycemia in the previous week and the median of each time point in the 7-point plasma glucose profile for 5 days were noted. These data were used for reinforcement of dietary advice and insulin dose adjustments.

Procedure and data collection

For both cohorts, maternal clinical data were collected at first pregnancy visit (early pregnancy visit) and at 35–37 weeks (late pregnancy visit). The women's *self-reported* weight and height before pregnancy, age at inclusion, duration of diabetes, gestational age at first visit, parity, ethnicity and smoking were noted.

The women were weighted on calibrated electronic scales without shoes or heavy clothes to the nearest 0.1 kg. Gestational weight gain was defined as the difference between measured weights at the early and the late pregnancy visits. Within the three BMI classes (normal weight (BMI<25 kg/m^2), overweight (BMI 25–29.9 kg/m^2) and obese (BMI≥30 kg/m^2)) gestational weight gain was categorized as follows based on the Institute of Medicine (IOM) 2009 recommendation[23]: insufficient (<11.5, <7.0 and<5.0 kg for the BMI classes, respectively), appropriate (11.5–16.0, 7.0–11.5 and 5.0–9.0 kg) and excessive (>16, >11.5 and >9 kg).

HbA1c was analyzed immediately by a DCA 2000 analyzer by a latex immunoagglutination inhibition method (DCA 200; Bayer, Mishawaka, IN). Delta-HbA1c was defined as the difference between the HbA1c measurements at the early and the late pregnancy visits. The urine was analyzed by Siemens CLINITEK Status+Analyzer. The occurrence of ketonuria was noted if the concentration of ketone bodies was ≥4.0 mmol/L. Diabetic retinopathy was assessed by retinal photoscreening and evaluated by an ophthalmologist. Diabetic nephropathy was defined as albumin-creatinine ratio ≥300 mg/g at the early pregnancy visit, based on two urine samples.

The data on maternal neck and ankle circumference and subcutaneous skinfolds were collected for the intervention cohort at the early and the late pregnancy visits. Neck circumference was obtained in a standing relaxed position in the midway of the neck, between mid-cervical spine and mid-anterior neck to within 1 mm. Ankle circumference was measured 5 cm above the lateral malleolus at both ankles as a pragmatic estimate for the development of peripheral edema. Skinfold thickness at four areas (biceps, triceps, suprailiac and subscapular) was measured to the nearest millimeters with a Harpenden caliper[24] and given as a sum of skinfolds.

Furthermore, the women answered two questions in a questionnaire: 'How motivated are you for achieving good glycemic control during pregnancy' and 'How motivated are you for achieving appropriate gestational weight gain during pregnancy' on a Likert scale from 1 to 10. A score ≥8 on the Likert scale was considered as very motivated. The coaches were motivated for using the motivational interviewing but were not asked about their own motivation.

The following data on pregnancy outcome were retrieved from the medical records: gestational age at delivery, preterm delivery (before 37 completed weeks), cesarean section (elective and emergency), shoulder dystocia and the sex of the infant. Weight, length, and abdominal and head circumference of the infant were measured shortly after birth. Birth weight z-score was calculated by local growth curves adjusted for gestational age and infant sex.[25] LGA and small for gestational age (SGA) were defined as birth weight >90th and <10th percentiles, respectively. As only half of the population was of Northern European origin, the prevalence of LGA and SGA infants was calculated by two different methods: first, by traditional Nordic growth curves[25] adjusted for gestational age and infant sex; second, by using customized birth weight centiles (gestation-related optional weight, GROW[26]) adjusted for maternal height, weight, ethnic origin, parity, gestational age and infant sex. Perinatal mortality (offspring death after 20 gestational weeks or within the first 7 days of life), major congenital malformations (leading to death, causing a substantial future handicap or requiring surgery), neonatal hypoglycemia

(defined as a plasma glucose value below 2.2 mmol/L, measured within 4 hours of life[27]), jaundice (requiring phototherapy), and transient tachypnea (requiring continuous positive airway pressure for more than 60 min) were noted. Perinatal morbidity was defined as the occurrence of at least one of the following complications: major congenital malformation, neonatal hypoglycemia, jaundice or transient tachypnea.

In addition, the infants in the intervention cohort had skinfold measurements of triceps, quadriceps, suprailiac and subscapular region measured to the nearest millimeter and performed with a Harpenden skinfold caliper[24] within 48 hours after birth.

Statistical analyses

Continuous data with normal distribution are reported as mean±SD, continuous data with skewed distribution as median (IQR) and categorical data as number (%). Comparison between the cohorts was performed by Student's t-test, Mann-Whitney U test, χ^2 test or Fisher's exact test where appropriate. To control for the following covariates from the early pregnancy visit: nulliparity, smoking, pre-pregnancy BMI and HbA1c (%), an analysis of covariance was used for comparison of gestational weight gain and birth weight z-score between the cohorts. Statistical analyses were performed with IBM SPSS Statistics V.22. Statistically significant differences were defined as a two-sided p<0.05.

A priori, we performed a simple power analysis. Based on our previous study,[5] we assumed a prevalence of LGA of 20% and 35% in the two cohorts and with a power of 80%, 135 women were needed in each cohort to detect a significant difference.

RESULTS

In total, 116 and 103 women were included in the intervention and the reference cohort, respectively. Thirteen women in the intervention cohort had a miscarriage and six women withdrew their consent, while in the reference cohort 10 women had a miscarriage and one woman moved from the uptake area, resulting in 97 (84%) and 92 (89%) women being included in the final analyses (figure 1A, B).

At the early pregnancy visit, the intervention cohort and the reference cohort were comparable regarding pre-pregnancy BMI, duration of diabetes, HbA1c and fraction on insulin treatment (tables 1 and 2).

The intervention cohort was very motivated to achieve good glycemic control and appropriate gestational weight gain where 85% and 84% scored ≥8 on a Likert scale at the early pregnancy visit and 77% and 72% at the late pregnancy visit, respectively.

The total gestational weight gain was 9.2±5.8 kg in the intervention cohort vs 10.2±5.8 kg in the reference cohort, p=0.25, corresponding to a weekly gestational weight gain of 0.26±0.16 kg vs 0.28±0.16 kg, p=0.31, respectively (table 2). The percentage of women with excessive gestational weight gain was 34.4% (32/93) in the intervention cohort and 45.4% (40/88) in the reference cohort (p=0.13) (table 2), corresponding to 24% fewer cases with excessive gestational weight gain in the intervention cohort compared with the reference cohort. After adjustment for nulliparity, smoking, pre-pregnancy BMI and HbA1c (%) from the early pregnancy visit, the difference in gestational weight gain between the cohorts remained insignificant (p=0.24). Few women lost weight during pregnancy in the two cohorts (table 2).

Within the intervention cohort the sum of maternal skinfold measurements and neck circumference was unchanged during pregnancy, while the ankle circumferences increased by 1.6 cm at each ankle, p<0.001 (table 2).

During pregnancy, most women in both cohorts were treated with insulin, and at the late pregnancy visit the median daily insulin dose per kilogram body weight was 0.95 (0.66–1.51) IU/kg in the intervention cohort compared with 0.74 (0.40–1.28) IU/kg in the reference cohort (p=0.03) (table 2).

HbA1c was comparable at the early pregnancy (6.7%±1.1% vs 6.5%±1.3% (50±12 mmol/mol vs 48±14 mmol/mol), p=0.32) and the late pregnancy (5.9%±0.5% vs 6.0%±0.6% (41±6 mmol/mol vs 42±7 mmol/mol),

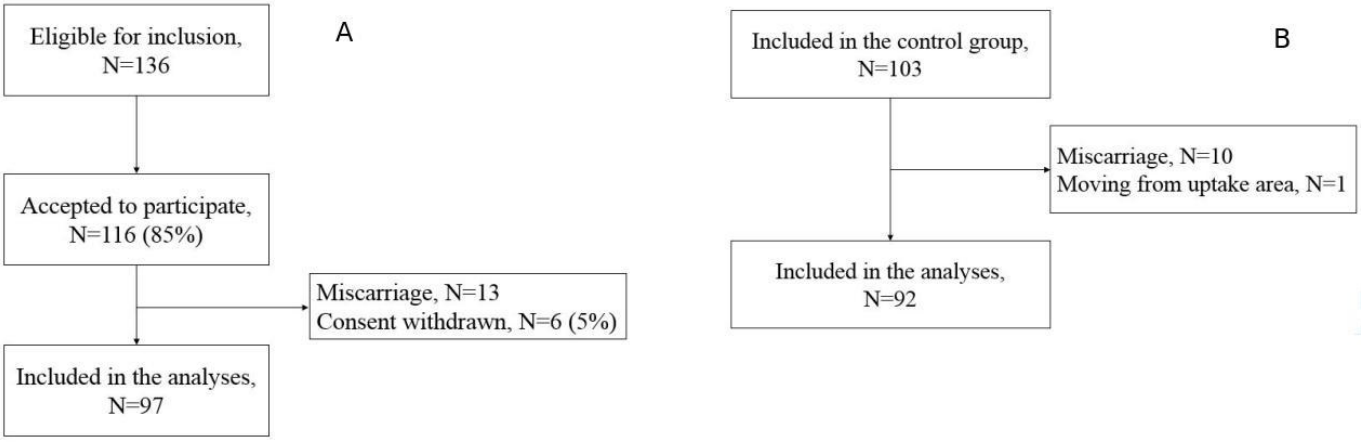

Figure 1 (A) Flowchart for inclusion in the intervention cohort. (B) Flowchart for inclusion in the reference cohort.

Table 1 Clinical characteristics among pregnant women with type 2 diabetes in the intervention cohort compared with the reference cohort at the early pregnancy visit

	Intervention cohort	Reference cohort	P value
n	97	92	
Age (years)	34±5	34±6	0.52
Duration of diabetes (years)	3 (1–8)	2.5 (0.5–5)	0.08
Diabetes retinopathy*	10 (12)	3 (5)	0.16
Diabetes nephropathy	1 (1)	0	1.00
North European origin	56 (58)	44 (48)	0.17
Nullipara	41 (42)	29 (32)	0.13
Smoker	10 (11)	18 (20)	0.13
Height (cm)	165.6±7.2	163.9±7.6	0.11
Pre-pregnancy BMI (kg/m^2)	32.8±6.9	32.4±7.4	0.70
BMI classes			
≤24.9 kg/m^2	14 (14)	17 (18)	0.75
25.0–29.9 kg/m^2	21 (22)	19 (21)	
≥30.0 kg/m^2	62 (64)	56 (61)	

Data are given as mean±SD, median (IQR) or n (%). Data available in 85%–100% unless otherwise stated.
*Data available from 87% vs 64%.
BMI, body mass index.

p=0.34) visits. However, the decline in HbA1c during pregnancy was greater in the intervention cohort compared with the reference cohort (−0.6 (−1.3 to −0.2)% vs −0.2 (−1.0 to 0.1)% (−7 (−14 to −2) mmol/mol vs −2 (−11 to 1) mmol/mol), p=0.01) (table 2).

The prevalence of LGA infants was 20% vs 31%, p=0.07, in the intervention cohort compared with the reference cohort (table 3). The figures when using the customized GROW curves, taking maternal characteristics into account, were 14% vs 27%, p=0.04 (table 3). The intervention cohort delivered infants with a birth weight z-score of 0.24±1.36 compared with 0.61±1.38 in the reference cohort (p=0.06). After adjustment for nulliparity, smoking, pre-pregnancy BMI and HbA1c (%) from the early pregnancy visit the difference in birth weight z-score remained insignificant between the cohorts (p=0.11). The occurrence of perinatal mortality and morbidity was similar in the two cohorts (table 3).

When restricting the analyses to the 86% of the intervention cohort judged compliant to the intervention, similar gestational weight gain, occurrence of LGA infants and birth weight z-score were obtained as for the total cohort (data not shown).

Transient tachypnea of the newborn tended to be less common in the intervention cohort compared with the reference cohort (10% vs 20%, p=0.06), while major congenital malformation (p=0.68), neonatal hypoglycemia (p=0.86) and jaundice (p=0.38) were comparable between the cohorts (table 3).

When dividing the cohorts into women of North European origin and non-North European origin, comparable gestational weight gain was obtained in the intervention cohort (9.2±6.0 kg vs 9.2±5.5 kg, p=0.96) and in the reference cohort (9.7±6.2 vs 10.7±5.4, p=0.42). The prevalence of LGA infants was 20% vs 20%, p=0.99, in the intervention cohort and 37% vs 26%, p=0.23, in the reference cohort, respectively, with the birth weight z-score of 0.11±1.25 vs 0.40±1.50, p=0.32, and 0.71±1.31 vs 0.52 vs 1.44, p=0.53.

CONCLUSIONS

In this cohort study consisting of an intervention cohort and a historical reference cohort there was a trend towards a reduced prevalence of fetal overgrowth, when using motivational interviewing to improve adherence to healthy eating in addition to routine care. The average gestational weight gain was comparable between the cohorts.

To our knowledge, this is the first lifestyle intervention study performed in pregnant women with type 2 diabetes.

Although the women in the intervention cohort received additional help to improve motivation for healthier eating habits, it was still challenging for many of the women to achieve appropriate gestational weight gain. However, we found a non-significant reduction in excessive gestational weight gain of 24%, which is comparable to the 23% reduction seen in healthy pregnant women exposed to dietary intervention[16] and lower than the 41%–63% previously reported in the literature.[5 13–15]

Three randomized controlled trials (RCT) using lifestyle intervention in healthy, overweight and obese pregnant women without diabetes found a reduced gestational weight gain of 1.5–2.3 kg in the intervention groups compared with the control groups[20 28 29] while three studies showed no effect on the gestational weight gain.[30–32] The obtained non-significant reduction in gestational weight gain of 1.0 kg in our study is thus close to what is obtained in healthy, overweight and obese women exposed to a lifestyle intervention.

The mean gestational weight gain in the intervention cohort was 9.2 kg, which is the same as the expected weight gain due to physiological changes in pregnancy, which has been estimated to 9.2 kg without taking the increase in maternal fat stores into account.[33] The women in the intervention cohort had documented a stable sum of skinfolds throughout pregnancy but developed signs of peripheral edema in late pregnancy, indicating that edema formation without increase in maternal subcutaneous fat mass can explain some of the obtained weight gain.

Most of the published lifestyle studies chose a combination of diet and physical activity changes as the intervention,[16] including the DALI study.[20] In the DALI study,

Table 2 Maternal glycemic control and weight changes during pregnancy among women with type 2 diabetes in the intervention cohort compared with the reference cohort

	Intervention cohort	Reference cohort	P value
Gestational age at the early pregnancy visit (days)	83±26	76±23	0.04
HbA1c at the early pregnancy visit (%)	6.7±1.1	6.5±1.3	0.32
HbA1c at the early pregnancy visit (mmol/mol)	50±12	48±14	
HbA1c at the late pregnancy visit (%)	5.9±0.5	6.0±0.6	0.34
HbA1c at the late pregnancy visit (mmol/mol)	41±6	42±7	
ΔHbA1c (%)*	−0.6 (−1.3 to −0.2)	−0.2 (−1.0 to 0.1)	0.01
ΔHbA1c (mmol/mol)	−7 (−14 to −2)	−2 (−11 to 1)	
Women with ketonuria at the early pregnancy visit (4–15.9 mmol/L)	2 (2)	5 (6)	0.25
Women with ketonuria at the late pregnancy visit (4–15.9 mmol/L)	2 (2)	3 (4)	0.67
Weight at the early pregnancy visit (kg)	91.9±22.0	89.6±23.5	0.48
Weight at the late pregnancy visit (kg)	101.3±21.3	100.3±23.8	0.78
Total gestational weight gain (kg)	9.2±5.8	10.2±5.8	0.25
Total gestational weight gain/week (kg)	0.26±0.16	0.28±0.16	0.31
Gestational weight gain according to IOM's recommendations			
Insufficient	29 (31.2)	24 (27.3)	0.31
Appropriate	32 (34.4)	24 (27.3)	
Excessive	32 (34.4)	40 (45.4)	
Women with weight loss during pregnancy	5 (5)	4 (5)	1.00
Neck circumference (cm)			
At the early pregnancy visit	37.5±4	–	0.24
At the late pregnancy visit	37.7±4	–	
Ankle circumference (cm)			
At the early pregnancy visit	24.1±3	–	<0.001
At the late pregnancy visit	25.7±4	–	
Sum of skinfolds (cm)†			
At the early pregnancy visit (cm)	11.2±3.1	–	0.29
At the late pregnancy visit	11.5±3.0	–	
Women on insulin treatment before the early pregnancy visit	21 (23)	24 (28)	0.43
Women on insulin treatment at the late pregnancy visit	89 (96)	77 (89)	0.07
Insulin dose at the late pregnancy visit (IU/kg)	0.95 (0.66–1.51)	0.74 (0.40–1.28)	0.03
Women with ≥1 episode of hypoglycemia the previous week at the late pregnancy visit‡	39 (47)	16 (28)	0.02

Data are given as mean±SD, median (IQR) or n (%). Data available in 87%–100% unless otherwise stated.
*ΔHbA1c was defined as the difference between measurements at the early and the late pregnancy visits.
†Sum of skinfold measurements of triceps, quadriceps, subscapular and suprailiac region.
‡Insulin-treated women only, with data available from 93% vs 74%, respectively.
IOM, Institute of Medicine.

a 2.3 kg lower gestational weight gain and reduced offspring adiposity measured by the sum of skinfolds was documented in the intervention group compared with the control group.[20 34] However, the compliance to the exercise part of the intervention has been documented low[28 35 36] and a reduction in physical activity during pregnancy is reported.[35 36] Aiming for a successful compliance to lifestyle changes, it is probably important to limit the number of tasks to change, and we asked the women to focus only on one of the dietary goals at a time. Whether the effect on gestational weight gain and fetal growth might have been more pronounced if goals for physical activity were added to the dietary intervention needs further investigation.

The intervention was not associated with a lower need for insulin; contrary, the intervention cohort received a higher insulin dose and had more often hypoglycemia at the late pregnancy visit compared with the reference cohort. Insulin is a growth factor and both insulin and hypoglycemia stimulate appetite and this may have influenced the effect on the gestational weight gain.

Table 3 Pregnancy outcomes among women with type 2 diabetes in the intervention cohort compared with the reference cohort

	Intervention cohort (n=97)	Reference cohort (n=92)	P value
Gestational age at delivery (days)	263 (260–270)	266 (259–268)	0.98
Preterm delivery (<37 weeks)	19 (20)	16 (17)	0.70
Cesarean section	44 (45)	46 (51)	0.48
Shoulder dystocia	1 (1)	1 (1)	1.00
Female offspring	41 (42)	48 (52)	0.17
Birth weight (g)	3167±659	3324±636	0.10
Birth length (cm)	50.4±3	50.5±2	0.85
Abdominal circumference (cm)	32.2±2	32.8±2	0.15
Head circumference (cm)	34.4±2	34.4±2	0.90
Sum of skinfolds (cm)*	2.21 (1.88–2.75)	–	
Birth weight z-score	0.24±1.36	0.61±1.38	0.06
Large for gestational age (Nordic curves)†	19 (20)	28 (31)	0.07
Small for gestational age (Nordic curves)†	11 (11)	5 (6)	0.16
Large for gestational age (GROW curves)‡	14 (14)	24 (27)	0.04
Small for gestational age (GROW curves)‡	14 (14)	7 (8)	0.15
Perinatal mortality	1 (1)	1 (1)	1.00
Perinatal morbidity§	34 (35)	37 (42)	0.39
Major congenital malformations	2 (2)	3 (3)	0.68
Neonatal hypoglycemia (<2.2 mmol/L)	15 (16)	14 (17)	0.86
Jaundice	15 (16)	10 (11)	0.38
Transient tachypnea	10 (10)	18 (20)	0.06

Data are given as median (IQR), n (%) or mean±SD. Only live births included and one woman in the reference cohort gave birth at another hospital and detailed data are missing. Data available from 87% to 100% if not otherwise stated.
*Sum of skinfold measurements of triceps, quadriceps, subscapular and suprailiac region, data on 58%.
†>90th and <10th percentiles using Nordic growth curves adjusted for gestational age and infant sex.
‡>90th and <10th percentiles using customized birth weight centiles adjusted for maternal height, weight, ethnic origin and parity in addition to gestational age and infant sex (gestation-related optional weight, GROW).
§Perinatal morbidity was defined as the occurrence of at least one of the following complications: major congenital malformation, neonatal hypoglycemia, jaundice and transient tachypnea.

The birth weight z-score is based on growth curves for a Nordic population.[25] Half of the women in this study were of other ethnic origin and therefore data on infant overgrowth are given both using the Nordic growth curves adjusted for gestational age and infant sex and the customized growth curves by GROW[26] where maternal height, weight, ethnic origin, parity, and gestational age and infant sex are taken into account, too. It is reassuring that the prevalence of LGA infants is similar regardless of the method used. The observed reduction in average birth weight z-score and the prevalence of LGA infants in this study is clinically meaningful. It did not convert to significantly reduced perinatal morbidity, but whether this reduction in fetal overgrowth will affect the long-term risk of obesity and type 2 diabetes later in life remains speculative. The occurrence of SGA infants in this study is close to the 10% expected in the background population.

Whether the more appropriate fetal growth in the intervention cohort could be explained mainly by motivational interviewing leading to healthier eating habits or whether the more intensive insulin therapy in the intervention cohort played the major role cannot be determined from our results. However, it is known that maternal lipids and protein consumption as well as micronutrients affect fetal growth.[37] It is possible that the women in the intervention cohort established overall better eating habits compared with the reference cohort, resulting in more appropriate fetal growth, not mediated by restricted gestational weight gain. Possible differences in nulliparity, smoking, pre-pregnancy BMI, and glycemic control between the groups at the early pregnancy visit have been taken into account by performing statistical analyses with and without these covariates.

The clinical benefits of avoiding transient tachypnea include better possibilities for skin-to-skin contact, maternal–child bonding and successful breast feeding. Both

fetal overgrowth and transient tachypnea of the newborn tended to be less common in the intervention cohort. Whether this is related to less fetal hyperinsulinemia needs to be clarified in further studies.

It is a strength that this cohort study included consecutive women with type 2 diabetes from a large population with very few exclusion criteria and was conducted in a real-world setting. Therefore, we are most likely studying an unselected population of pregnant women with type 2 diabetes, also including the vulnerable women from more deprived areas. This makes the study results applicable to the relevant population. In an RCT, vulnerable women would often not participate even though they probably were the ones needing motivation for lifestyle changes the most. Another potential problem with an RCT including lifestyle interventions is the Hawthorne effect, that is, the women accepting inclusion are often very motivated, which results in improved lifestyle in the control group, too. This is not the case in our study where a historical cohort that was totally unaware of the intervention was included. The study was planned with a minimal excess use of one-to-one contact with a caregiver and the women followed their routine visits, enabling the women to participate regardless of parity, economy or occupation. Furthermore, this enables the motivational interviewing technique to be implemented as routine care. However, resources of an extra diabetes caregiver of approximately 240 min per women were applied.

By including measurements of maternal skinfolds and ankle circumferences, we obtained a rough estimate of changes in maternal subcutaneous fat and fluid retention.

The limitation of ending up with insufficient numbers of women in this study was sought minimized by including women at two centers over a 2.5-year inclusion period. However, a large proportion of our pregnant women with type 2 diabetes had insufficient Danish skills and could for ethical reasons not be included.

A participation in a clinical trial often enhances general awareness of the participant and the caregiver and it is possible that there has been more focus on appropriate insulin treatment in the intervention cohort. On the other hand, healthy eating may reduce hyperglycemia and enable the women to obtain more sufficient insulin treatment without suffering from pronounced hypoglycemia.

An evaluation of the maternal food intake including carbohydrate, fat and protein intake as well as physical activity would have improved the study.

The lifestyle coaches were two midwives with special education and training in the motivational interviewing with focus on healthy eating and had years of experience from the DALI study where using midwifes was documented effective.[20] The women in both cohorts received dietary guidance by a registered dietitian according to local practice. Whether training of the local dietitian in the motivational interviewing would have given different results remains speculative.

The goals for the gestational weight gain for the women in both cohorts were according to the Copenhagen guidelines that are stricter than the IOM guidelines. However, the weight gain was given as insufficient/appropriate/excessive according to the IOM guidelines in order to compare the results with other studies.

In conclusion, motivational interviewing to improve adherence to healthy eating in addition to routine care in women with type 2 diabetes tended to reduce fetal overgrowth without major effect on gestational weight gain. Further studies investigating the cost-benefit of enhancing motivation for adherence to treatment goals are needed.

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Contributors BÁ contributed to the idea, collected and researched the data, wrote the manuscript and contributed to the discussion. MV collected the data, contributed to the discussion and reviewed and edited the manuscript. LR, LLTA, and DMJ contributed to the discussion and reviewed and edited the manuscript. PD and ERM contributed to the idea and discussion and reviewed and edited the manuscript. ERM is the guarantor of this work and as such had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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