The effect of a counselling intervention on weight changes during and after pregnancy: a randomised trial

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Abstract

Objectives: To evaluate the effects of a counselling intervention on excessive weight gain during pregnancy and postpartum weight retention.

Design: The New Life(style) study was a randomised trial with a control group (n = 113) and an intervention group (n = 106).

Setting: Midwife practices in the Netherlands.

Population: Women with a healthy pregnancy, expecting their first baby.

Main outcome measures: Weight was objectively assessed at 15, 25 and 35 weeks of gestation, and again at 8, 26 and 52 weeks postpartum. In regression models, the intervention effect on gestational weight gain and postpartum weight retention was assessed.

Results: Women gained on average 11.3 kg (SD 3.7 kg) from early to late pregnancy. Women were 1.0 kg (SD 5.3 kg) lighter at 52 weeks postpartum compared with early pregnancy. The intervention had no effect on gestational weight gain (B = −0.05; 95% CI −1.10 to 1.00) or postpartum weight (B = 0.94; 95% CI −2.41 to 0.53) in the total study group. In a subgroup of overweight and obese women (n = 47) a favourable trend on all outcomes was observed, but none of the differences were statistically significant.

Conclusions: The lifestyle counselling intervention evaluated in this study did not have an effect on excessive weight gain or postpartum weight retention. Our findings for overweight and obese women need to be confirmed in a larger, well-designed randomised trial.
Introduction

The period during and after pregnancy represents an important window of opportunity for overweight prevention (1–3). From conception to 1 year after having given birth, women gain on average between 0.5 and 3 kg in weight, and 12–25% of women have a weight retention of more than 5 kg postpartum (4–7). Postpartum retained fat appears to be deposited centrally, rather than peripherally (7,8).

Gestational weight gain is a major predictor of postpartum weight retention (5,6,7,9,10). In 1990 the Institute of Medicine (IOM) formulated body mass index (BMI) specific recommendations for healthy gestational weight gain (11) and in 2009 these recommendations were revised for obese women (12). Women who gain more weight during pregnancy than recommended are more likely to retain weight (13,14). Therefore, prevention of excessive weight gain during pregnancy is important in the prevention of overweight and obesity in women of childbearing age.

In meta-analyses it was shown that interventions consisting of counselling on physical activity and diet, or physical activity alone, could have a small effect on gestational weight gain (15,16). However, in other reviews, including more or less the same studies, the conclusions were a bit more cautious. Skouteris et al. argued that the evidence was not convincing, as almost none of the studies reported intervention effects across all BMI groups of pregnant women (17). Ronnberg et al. concluded in their systematic review that the evidence for the effectiveness of these interventions was very low, because of the insufficient quality of the studies and inconsistent results (18).

The aim of this study was to evaluate the effects of a counselling intervention on excessive weight gain during pregnancy and postpartum weight retention.

Methods

Design

The New Life(style) study was a randomised trial with a control group and an intervention group. The participating women were studied during a period of 18 months: from 15 weeks of gestation until 1 year after delivery. The design of the study is described in detail elsewhere (19). The Medical Ethics Committee of VU University Medical Centre has approved the study design, protocols and informed consent procedure.

Randomisation

Women were individually randomised to the intervention or control groups. A computerised random number generator drew up an allocation schedule pre-stratified for midwifery practices.
Within each stratum, allocation was equally divided between intervention and control groups. After the baseline measurement, participants were informed about which group they were assigned to.

**Participants**
This trial was carried out in eight midwifery practices in the Netherlands. From February 2005 until May 2006, midwives invited women expecting their first baby to participate, and if interested the research team was informed. After introducing the study, midwives indicated a possible interest on a reply coupon, and send this coupon to the research team. A research assistant contacted the interested women within 2 weeks, and provided more detailed information explaining the aim of the study and checking the eligibility criteria. Women were eligible for participation when they were: [1] expecting their first child; [2] able to read, write and speak Dutch; [3] in the first 14 weeks of gestation. Informed consent forms were obtained from each participant.

**Intervention**
The New Life(style) intervention programme consisted of five individual counselling modules. In the modules the counsellors discussed how to control weight gain during and after pregnancy, and how to maintain or optimise a healthy lifestyle in a period of physical and mental changes. Women attended these counselling sessions over a period of 30 weeks, with face-to-face appointments at 18, 22, 30 and 36 weeks of gestation, and with a telephone session at 8 weeks postpartum. Each counselling session took about 15 minutes, except for the first session, which took approximately half an hour, in which the aim of the study and the intervention was explained again. The content of the first module was summarised in an information brochure, which was handed out to the participants after the first counselling session. The content of the counselling sessions is described in detail by Althuizen et al (19). The counsellors were members of the research team.

**Co-interventions and compliance**
The participating midwives were asked not to take part in other research programmes in order to prevent possible interference from co-interventions. Compliance with the intervention programme was assessed by registering the number of counselling sessions attended by the participants.

**Measurements**
Participants in both the intervention and control group were invited for six measurement sessions in the period during and after pregnancy. Data were collected at 15 (baseline), 25 and 35 weeks of gestation, and again at 8, 26 and 52 weeks after delivery. On these occasions
anthropometrical measurements were carried out by research assistants, blinded to treatment allocation. All participants received questionnaires by mail 1 week before each measurement session. They were asked to bring along the completed questionnaires. The assistant then checked the questionnaires for missing data.

**Primary outcome measures**

**Body weight and BMI**

Body height was measured on bare feet by means of a wall-mounted height scale (SECA 206), to an accuracy of 0.1 cm. Calibrated electronic scales (SECA 888) were used to determine the body weight of the participants in their underwear, with an accuracy of 0.1 kg. Both weight and height were measured twice, and the mean value of the two measurements was computed and used to calculate the individual BMIs (kg/m²). The prepregnancy BMI category was based on self-reported prepregnancy weight and objectively measured height.

For weight gain during pregnancy, both continuous and dichotomous outcome measures were calculated. The continuous measure was weight at 35 weeks of gestation minus weight at 15 weeks of gestation. The dichotomous measure was weight gain in excess of the recommendations, and was assessed based on the weight gained between 15 and 35 weeks of gestation. For each BMI category, the maximum weekly recommended weight gain (0.58 kg per week for underweight, 0.50 kg per week for healthy weight, 0.33 kg per week for overweight and 0.27 kg per week for obese women) was multiplied with the number of weeks between the two measurements (12). Excessive weight gain was defined as a weight gain in excess of this maximum recommended weight gain.

Also, for the outcome of weight change after delivery, continuous and dichotomous variables were calculated. The continuous variable was weight at 52 weeks after delivery minus weight at 15 weeks of gestation. The dichotomous variable representing substantial weight retention was calculated as a change of 3 kg or more from 15 weeks of gestation to 52 weeks after delivery.

**Neonatal outcomes**

Birthweight was self-reported by the women in the questionnaire they received 8 weeks after delivery. Macrosomia was defined as a birthweight of 4 kg or more. Also, data on preterm birth (<37 weeks of gestation) and gestational diabetes (GDM) were reported in the questionnaire at 8 weeks postpartum.
Covariates
In the questionnaires at 15 weeks of gestation, education and self-reported prepregnancy BMI were assessed. Education was dichotomised into whether or not women had completed further education after high school.

Sample size
The aim was to include 276 participants in the study. In order to be able to detect a difference in BMI of 0.8 kg/m² at 6 months postpartum between the intervention group and the control group, 220 participants were needed: 110 participants in each group. These numbers were based on a power ($1 - \beta$) of 0.80, a significance level of 0.05 (two-sided) and a standard deviation of 2.0 kg/m². Accounting for a drop-out of 20%, the aim was to randomise 138 women to each of the two research groups.

Statistical analysis
Based on the intention-to-treat principle, all participants were analysed according to the group they were assigned to, regardless of whether they received the intervention or not. Missing data were not imputed. Multilevel regression analyses were performed in MLwiN 2.0, taking into account clustering within midwife practices. Logistic regression analyses were used in examining the dichotomous outcome measures of gestational weight gain in excess of recommendations and substantial weight retention. Exponentiated regression coefficients for group allocation variables (0, control; 1, intervention) reflected cluster-specific odds ratios (ORs) (20). Linear regression analyses were used in assessing continuous outcome measures. Regression coefficients for group allocation variables (0, control; 1, intervention) reflected average differences between intervention groups in the outcome variables. All analyses were controlled for age, education level (defined as high or low) and prepregnancy BMI. Analyses of gestational weight gain and birthweight were additionally controlled for number of weeks between measurements and gestational age at birth, respectively. Age, education and prepregnancy BMI were also considered as possible effect modifiers. Effect modification was defined as a significant ($P < 0.10$) interaction between group allocation and the variable in question. Only significant effect modifiers are discussed in the Results. For the analyses of effects postpartum, women who were pregnant again were excluded.

Results

Study sample
Of the 708 women who were invited to participate in the study, 688 (97%) returned the recruitment reply card. Of these, 232 (34%) could not or declined to participate, and 210 (31%)
were excluded for various reasons (Figure 1). A total of 246 women (36%) were available for the baseline measurement, and were randomised. The flow of participants through the study and the distribution of non-responders are shown in the Flowchart of participants (Figure 1).

Figure 1. Flow chart of participants.

The effect of a counselling intervention on weight changes during and after pregnancy | 41
For the purpose of this paper, only the 219 participants (106 in the intervention group and 113 in the control group) that provided data at baseline and at 35 weeks of gestation were selected for analyses. Table 1 presents the characteristics of the population under study at baseline.

### Table 1. Characteristics of the study sample

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( n = 106 )</td>
<td>( n = 113 )</td>
</tr>
<tr>
<td>Age, y, mean (SD)</td>
<td>29.2 (3.8)</td>
<td>30.4 (4.0)</td>
</tr>
<tr>
<td>Marital status, ( n ) (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/living together</td>
<td>100/106 (94)</td>
<td>108/111 (97)</td>
</tr>
<tr>
<td>Single</td>
<td>6/106 (6)</td>
<td>3/111 (3)</td>
</tr>
<tr>
<td>Education, ( n ) (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>51/106 (48)</td>
<td>47/111 (42)</td>
</tr>
<tr>
<td>High</td>
<td>55/106 (52)</td>
<td>64/111 (58)</td>
</tr>
<tr>
<td>Employment, ( n ) (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed/student</td>
<td>100/106 (94)</td>
<td>105/111 (95)</td>
</tr>
<tr>
<td>Non-employed</td>
<td>6/106 (6)</td>
<td>6/111 (5)</td>
</tr>
<tr>
<td>Country of birth, ( n ) (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Netherlands</td>
<td>97/106 (92)</td>
<td>105/111 (95)</td>
</tr>
<tr>
<td>Other</td>
<td>9/106 (8)</td>
<td>6/111 (5)</td>
</tr>
<tr>
<td>Height, cm, mean (SD)</td>
<td>169.1 (6.6)</td>
<td>169.3 (6.7)</td>
</tr>
<tr>
<td>Pre-pregnancy BMI, kg/m2, mean (SD)</td>
<td>24.0 (4.2)</td>
<td>23.5 (3.8)</td>
</tr>
<tr>
<td>Pre-pregnancy BMI category, ( n ) (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underweight</td>
<td>11/106 (10)</td>
<td>15/111 (14)</td>
</tr>
<tr>
<td>Healthy weight</td>
<td>70/106 (66)</td>
<td>74/111 (67)</td>
</tr>
<tr>
<td>Overweight</td>
<td>10/106 (9)</td>
<td>9/111 (8)</td>
</tr>
<tr>
<td>Obese</td>
<td>15/106 (14)</td>
<td>13/111 (12)</td>
</tr>
</tbody>
</table>

Attendance for the counselling sessions was high. Seven of the 123 women (6%) randomised to the intervention group attended none or only one counselling session, 10 women (8%) attended two or three counselling sessions, 23 women (19%) attended four sessions and 83 women (67%) attended every session. The fourth session was the session missed by most women because they had already delivered.

**Effect on weight gain during pregnancy**

No baseline differences in weight were observed between the intervention group and the control group (Table 2). From 15 to 35 weeks of gestation, women gained on average 11.3 kg (SD 3.7 kg). In the linear regression models, no significant between-group differences were found in weight changes during pregnancy (\( B = -0.05; \) 95% CI \(-1.10\) to \(1.00\)). A total of 145 women (71%) gained more than the recommended weight between 15 and 35 weeks of gestation. In logistic regression analyses, no intervention effect on the percentage of women gaining in excess of the recommended range was observed (\( OR = 0.92; \) 95% CI \(0.48–1.77\)).
**Effect on weight changes postpartum**

Women were on average 1.0 kg (SD 5.3 kg) lighter at 52 weeks postpartum than they were at 15 weeks of gestation (Table 2).

<table>
<thead>
<tr>
<th>Weight, kg (SD)</th>
<th>Pre-pregnancy*</th>
<th>Pregnancy</th>
<th>Postpartum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>67.4 (11.6)</td>
<td>71.4 (12.4)</td>
<td>71.1 (13.3)</td>
</tr>
<tr>
<td>Intervention</td>
<td>68.6 (13.4)</td>
<td>71.4 (13.5)</td>
<td>72.9 (14.9)</td>
</tr>
</tbody>
</table>

* self-reported data on prepregnancy weight

In Figure 2, the BMI distribution in early pregnancy and at 52 weeks postpartum is presented.

**BMI distribution in early pregnancy and 52 weeks postpartum**

In linear regression models, no intervention effects were found on weight change postpartum (B = 0.94; 95% CI −2.41 to 0.53; Table 3). Twenty-nine women (15%) retained more than 3 kg from 15 weeks of gestation to 52 weeks postpartum. No differences were found between the intervention and the control group (OR 1.20; 95% CI 0.41–3.51).
Table 3: Weight changes during pregnancy and postpartum by treatment group and results of multilevel analyses of treatment effects

<table>
<thead>
<tr>
<th>Weight changes</th>
<th>Control group</th>
<th>Intervention group</th>
<th>Beta or OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight change 15-35 wks pregnancy, kg (SD)</td>
<td>11.1 (3.2)</td>
<td>11.6 (4.1)</td>
<td>B = -0.05*</td>
<td>-1.10 – 1.00</td>
</tr>
<tr>
<td>Weight gain in excess of recommended range, %</td>
<td>72.4%</td>
<td>70.4%</td>
<td>OR = 0.92</td>
<td>0.48 – 1.77</td>
</tr>
<tr>
<td>Weight change postpartum, kg (SD)</td>
<td>-1.75 (5.1)</td>
<td>-0.53 (5.5)</td>
<td>B = 0.94</td>
<td>-2.41 – 0.53</td>
</tr>
<tr>
<td>Substantial weight retention &gt; 5 kg, %</td>
<td>12.2%</td>
<td>19.4%</td>
<td>OR=1.20</td>
<td>0.41 – 3.51</td>
</tr>
</tbody>
</table>

Results from multilevel analyses, taking into account clustering within midwife practices. All regression models were controlled for age, education and prepregnancy BMI.
*analyses in addition controlled for number of weeks between the two measurements

**Effect on neonatal outcomes**

The mean birthweight was 3489 g (SD 464 g), with a higher birthweight in the intervention group compared with the control group (Table 4) (B = 147.3; 95% CI 6.2–288.4). A total of 35 out of 210 neonates (17%) had a birthweight of >4 kg, and the percentage of neonates with macrosomia did not differ between the intervention group and the control group. No differences between intervention and control groups were observed in the number of premature neonates or caesarean sections.

Table 4. Neonatal and pregnancy outcomes by treatment group and results of regression analyses of treatment effects.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control group (n=107)</th>
<th>Intervention group (n=103)</th>
<th>B or OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth weight, g, mean (SD)</td>
<td>3431 (456)</td>
<td>3550 (466)</td>
<td>B = 147.3*</td>
<td>6.2 – 288.4</td>
</tr>
<tr>
<td>Macrosomia (&gt; 4 kg), %</td>
<td>14%</td>
<td>19%</td>
<td>OR = 1.60*</td>
<td>0.76 – 3.41</td>
</tr>
<tr>
<td>Preterm delivery (&lt; 37 wk), %</td>
<td>7%</td>
<td>6%</td>
<td>OR = 0.94</td>
<td>0.27 – 3.35</td>
</tr>
<tr>
<td>Caesarean delivery, %</td>
<td>21%</td>
<td>16%</td>
<td>OR = 0.60</td>
<td>0.29 – 1.25</td>
</tr>
</tbody>
</table>

Results from multilevel analyses, taking into account clustering within midwife practices. All regression models were controlled for age, education and prepregnancy BMI.
* analyses in addition controlled for gestational age.

**Subgroup analysis**

Prepregnancy BMI proved to be an effect modifier in our analyses, and therefore subgroup analyses based on prepregnancy BMI were performed. Because of the low numbers in the underweight and in the obese categories, the groups of underweight and healthy weight women (n = 172) and the groups of overweight and obese women (n = 47) were combined.
No differences in the underweight/healthy weight group were found between intervention and control groups. However, in the overweight/obese group, a trend was observed in favour of the intervention group for all outcome measures, but none of the differences were statistically significant. Overweight and obese women in the intervention group gained less weight during pregnancy compared with the control group: 10.6 kg (SD 5.2 kg) versus 12.1 kg (SD 3.8 kg), respectively. Fewer women in the intervention group gained in excess of the recommendations compared with the control group (75 versus 100%).

Postpartum, this effect in favour of the intervention group was not observed. At 52 weeks postpartum, women in the control group weighed 0.33 kg (SD 8.9 kg) more compared with 15 weeks of gestation, and women in the intervention group weighed 1.4 kg (SD 7.8 kg) more at the same time point. We found that 31.8% of the women in the control group and 35.7% of women in the intervention group had substantial weight retention. None of these postpartum differences were statistically significant.

**Discussion**

In this randomised trial aiming at preventing excessive gestational weight gain in women delivering their first child, a counselling intervention had no effect on weight gain during pregnancy or weight retention postpartum. In a small subgroup of overweight or obese women the intervention seemed to have some effect on outcomes in pregnancy, but this effect was not statistically significant.

Results of similar previous studies were mostly in line with the results from the present study: most did not find statistically significant effects on gestational weight gain overall (15,17,18). Also, in a recent randomised controlled trial (RCT) evaluating the effect of a behavioural intervention to prevent excessive gestational weight gain, no statistically significant effect on average weight gain was found, although among normal weight women, more women in the intervention group compared with the control group gained weight within the IOM recommendations (21).

Research on the effects of antenatal interventions on long-term postpartum weight retention is relatively scarce. Two RCTs have been published, assessing weight retention very shortly after delivery (at 6 and 4 weeks postpartum, respectively) (22,23). Their results were inconsistent. A longer postpartum follow-up was reported on by Phelan, who found that at 6 months postpartum the mean weight retention did not differ between intervention and control groups, but that a higher percentage of women in the intervention group had returned to, or dropped below, their prepregnancy weight (21). Also, in the study presented here, no differences were found between intervention and control groups in mean weight changes postpartum.
The data in this study suggest that the intervention might be successful in reducing gestational weight gain in a subgroup of overweight and obese women, but more evidence is needed. Dodd et al. reviewed antenatal interventions for overweight and obese women (24). Combining the results of four RCTs on gestational weight gain, the interventions resulted in a non-significant weighted mean difference of −3.10 kg. Although three out of four showed results in favour of the intervention group, this was only significant in one study. In this study, which was also the only study with sufficient power, a significant reduction in weight gain of 7.90 kg was reported in the intervention group (25). Based on the findings of this review and the findings presented here, we think it is useful to conduct another well-designed RCT with sufficient power among overweight and obese pregnant women to clarify the effect of antenatal interventions among the group of overweight and obese pregnant women.

The strengths and limitations of this study must be noted. A major limitation of this study is the aforementioned highly selective sample of participating women. They were not reflective of all Dutch pregnant women, as they were highly educated and almost none of them came from an ethnic minority. As women from Dutch origin gain on average less weight in pregnancy and retain less weight postpartum, the changes in weight described here are likely to be an underestimation (26). Selection of the sample will not effect the reliability of the absence of an intervention effect, but compliance with the intervention, which was high in this study, might be lower in groups with lower socio-economic status.

Another limitation of this study is that no objective data on prepregnancy weight or BMI were available, and that the first measurement was only made early in the second trimester. Objective information on weight gain in early pregnancy is therefore lacking. Total postpartum weight retention is likely to be higher than presented here, as we used the weight at 15 weeks of pregnancy, and women will already have gained between 0.5 and 2 kg by that time (27-29). Also, the total gestational weight gain could not be assessed in the study, as the last measurement was taken at 35 weeks of gestation. When interpreting data on postpartum weight retention, it must also be kept in mind that women in the general population would also have gained weight over a period of 18 months, as a natural effect of ageing (30). Further limitations were the lack of binding of participants to the intervention. Also, missing data were not imputed in the analyses; therefore, the intention-to-treat principle was only partially implemented. However, we do not feel that this influenced our results. Finally, we might have lacked some power to detect differences between groups, as the sample was smaller than calculated in the sample size calculations. Clustering within practices was negligible: intraclass correlation coefficients were 0 for the majority of the outcome variables, and were maximally 0.04 (for postpartum weight retention). Therefore, clustering will not have greatly affected the statistical power. This finding can be used for sample size calculations in future studies. Strengths of this study include the long postpartum follow-up of 52 weeks, and the objective measurements of weight in that period.
Reasons for the lack of effect of the intervention could be found in the methodological problems described above, but also at the level of the intervention itself. We conducted an extensive process evaluation, which showed that, despite the presence of an intervention protocol and counsellor training, not all of the intended counselling components were delivered (31). Although 83% of women attended all sessions, the dose of intervention components received was moderate (45.8–60.3%), and the dose of problem solving treatment (PST) components was low (17.3%). Furthermore, although the PST theory was the basis of the intervention, the participants were rarely involved in ‘problem solving’. This could have led to less effective counselling, and might (partly) explain the lack of effect.

In conclusion, the behavioural counselling intervention that we used in this study had no statistically significant effect on weight gain or weight retention in a group of women expecting their first child. The observed effects for overweight or obese women need to be confirmed in larger studies. At the moment, no recommendations for health care professionals involved in prenatal and antenatal care can be formulated.
References