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6 Gestational weight gain is often excessive and early in pregnancy
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3 1 Abstract
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5 2 Background: Gestational weight gain (GWG) in excess or below Health Canada's guidelines is
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7 3 known to increase the risk of adverse outcomes for mother and baby. This study describes
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9 4 patterns and trajectories of total and rates of GWG in a large prospective cohort of pregnant
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11 5 women from Alberta.
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13 6 Methods: Body weight and height data was collected from 1541 pregnant women (>16 years,
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15 7 literate in English, <27 weeks gestation) during 2 – 3 study visits. Women were categorized
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17 8 according to their pre-pregnancy body mass index (BMI; underweight, normal, overweight,
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19 9 obese). Distributions of total and weekly rates of weight gain were calculated and trajectories of
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21 10 weight gain were determined for each pre-pregnancy BMI category.
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25 11 Results: Half of the women in this study exceeded GWG guidelines; 18% gained less than
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27 12 recommended. For those with an overweight or obese pre-pregnancy BMI, 19% and 24%
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29 13 exceeded the upper guideline limits by 50l □kg while 16% and 18% exceeded upper limits by
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31 14 >1 □kg, respectively. Approximately one third of overweight and obese women gained weight at
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33 15 more than double the recommended rates. Median weight gain for women with normal,
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35 16 overweight or obese pre-pregnancy BMIs exceeded recommended upper ranges by 3 □, 2 □and 18
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37 17 weeks respectively.
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41 Interpretation: Comprehensive information on patterns of GWG in Canadian women will help
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43 to guide the development of effective clinical interventions. Messages and supports that are
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45 tailored for women in different pre-pregnancy BMI categories may help to improve guideline
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47 concordant GWG. Further research is needed to identify best practices and implementation
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49 strategies in the Canadian context.
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4 19 Introduction
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6 20 Inadequate or excessive weight gain during pregnancy increases risk of adverse outcomes for
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8 21 mother and baby. Gaining too little weight has been associated with higher risk of infant death¹
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10 22 and being small for gestational age.² Gaining too much weight increases the risk of postpartum
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12 23 weight retention³ and caesarian delivery⁴, and may also increase the risk of gestational
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14 24 hypertension in mothers⁴, and large for gestational age infants.⁵
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16 25 In 2014, Health Canada adopted and disseminated the updated guidelines for gestational weight
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18 26 gain (GWG) that had been developed by the Institute of Medicine (see Box 1).^{6,7} These
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20 27 guidelines are intended to support physicians and clinicians who practice in the area of prenatal
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22 28 care by providing appropriate ranges for total and weekly rates of GWG, based on women's pre-
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24 29 pregnancy body mass index (BMI).
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26 30 The impetus for revising the guidelines was growing recognition that excessive weight gain in
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28 31 pregnancy is becoming increasingly prevalent. Typically, women in developed countries who
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30 32 gain too much weight are likely to have entered pregnancy with a BMI that classifies them as
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32 33 overweight or obese.^{8,9} However, more recent studies have demonstrated that excessive GWG
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34 34 is also prevalent in women with a normal pre-pregnancy BMI and it also occurs in underweight
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36 35 women, albeit to a lesser extent.^{4,12,13} To date, the majority of studies in this area have focused
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38 36 on total GWG, with little consideration given to the trajectory of weight gain during the course
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40 37 of pregnancy. Furthermore, many studies have simply classified women into three categories of
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42 38 'below', 'met' or 'above' guidelines, and few have described the distribution of weight gain
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44 39 within groups of women according to pre-pregnancy BMI category. It is clear that more
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46 40 comprehensive information on patterns of GWG is needed in order to help identify women who
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4 41 may be at risk of not meeting GWG guidelines, and to guide the development of more effective
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6 42 strategies for intervention.

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8 43 The objective of the current study was to describe patterns of total and rate of GWG in a cohort
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10 44 of pregnant women in Alberta, Canada relative to Health Canada's revised GWG guidelines.

11 12 45 Methods

13 14 46 Study design and population

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17 47 The Alberta Pregnancy Outcomes and Nutrition (APrON) study is a prospective cohort study of
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20 48 women during pregnancy and postpartum and their infants. Details of participant recruitment and
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22 49 study protocols have been published elsewhere.^{14,15} In brief, participants were recruited through
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25 50 advertisements in the media and in physician offices in Calgary and Edmonton, Alberta between
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27 51 May 2009 and November 2012. Eligibility criteria were: aged 16 years or older, literate in
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29 52 English and <27 weeks gestation. Women who provided written informed consent were invited
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32 53 to attend a study centre once in each trimester following enrollment, and once at approximately
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34 54 three months postpartum. Ethical approval for the APrON study was obtained from the Health
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36 55 Research Ethics Boards at the University of Alberta and the University of Calgary.

37 38 56 Procedure

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41 57 Upon enrollment, participants completed questionnaires concerning pre-pregnancy weight, age,
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43 58 parity, marital status, ethnicity, family income, and education. At each study centre visit, trained
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45 59 staff measured participant weight to the nearest 0.1 kg (Healthometer Professional 752KL), and
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47 60 height to the nearest 1 cm (Charder HM200P Portstad Portable Stadiometer). Pre-pregnancy
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49 61 BMI was calculated using self-reported pre-pregnancy weight and measured height and women
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51 62 were classified as underweight (BMI < 18.5 kg/m²), normal weight (18.5 ≤ BMI < 25 kg/m²),
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4 63 overweight ($25 < \text{BMI} < 30 \text{ kg/m}^2$), or obese ($\geq 30 \text{ kg/m}^2$). Self-reported highest weight in pregnancy
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6 64 was recorded at the postpartum visit.

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8 65 **Outcome measures**

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10 66 Weight change throughout pregnancy was calculated as the difference between self-reported pre-
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12 67 pregnancy body weight and measured weight at each study centre visit. Total GWG was
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14 68 calculated by subtracting pre-pregnancy body weight from the highest body weight during
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16 69 pregnancy. In cases where participants either did not report their highest body weight or reported
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18 70 a weight that was lower than had been measured during the 3rd trimester, we calculated total
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20 71 GWG using measured weight in the 3rd trimester. Weekly average weight gain during the 2nd
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22 72 and 3rd trimesters was calculated by subtracting measured weight in the 2nd trimester from
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24 73 measured weight in the 3rd trimester, and dividing by the number of intervening weeks.
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26 74 Participants with missing values for either 2nd or 3rd trimester measured weight were excluded
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28 75 from this weight gain rate analysis.

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30 76 **Statistical analysis**

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32 77 Within each pre-pregnancy BMI group, women were categorized as “below” if they gained less
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34 78 than the lower limit of the recommended amount of total weight, “met” if they gained within the
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36 79 recommended weight range, or “above” if they exceeded the upper limit of the recommended
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38 80 amount of weight gain. Information from the infants birth record was used to classify infants as
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40 81 small for gestational age (SGA) or large for gestational age (LGA). SGA is defined as being $< 10^{\text{th}}$
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42 82 percentile for gestational age and LGA is defined as being $> 90^{\text{th}}$ percentile for gestational age.
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44 83 The association between SGA and LGA and GWG guideline adherence were assessed using a χ^2
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46 84 test.
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4 85 Women were also categorized as “below”, “met”, or “above” according to their adherence to
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6 86 guidelines for average weekly rate of weight gain during the 2nd and 3rd trimesters. The
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8 87 distributions of total and weekly rate of GWG by pre0pregnancy BMI category, as well as
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10 88 proportions of women who were $50 < 1 \square \text{kg}$, $1 \square 0 15 \text{ kg}$ and $> 15 \text{ kg}$ over the upper recommended
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12 89 limit for their pre0pregnancy BMI category were calculated. Box plots were used to explore the
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14 90 trajectory of weight gain throughout pregnancy, with each box indicating the median and
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16 91 interquartile range of weight gain within the range of gestational ages. Cut0ff points for
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18 92 gestational age were selected such that the range of time for each box was as small as possible
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20 93 but had a minimum of 16 observations per box. The guideline ranges were superimposed on to
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22 94 each box plot to facilitate comparisons between observed and recommended GWG trajectories.
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27 95 Results
28
29 96 In total, 2189 pregnant women were recruited to the APrON study. The median GA at the time
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31 97 of enrollment was 16.6 weeks (IQR: 1402 16 weeks). Those included in our analyses (n=1541)
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33 98 gave birth to a single, live, full term (≥ 37 weeks gestation) infant and had complete data for
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35 99 GWG and pre0pregnancy weight status (Figure 1). Participants excluded from these analyses did
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37 100 not differ in socio0demographic and health0related characteristics from those who were included
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39 101 (data not shown).
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43 102 Sensitivity analyses were undertaken to explore the utility of using self0reported pre0pregnancy
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45 103 weight to calculate BMI. BMI derived from height and weight measured in 528 participants
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47 104 recruited during the first trimester was compared with BMI derived for the same women using
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49 105 measured height and self0reported pre0pregnancy weight. Almost all (99%) women categorized
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51 106 as obese using measured values were placed in the same category when self0reported weights
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4 107 were used to derive BMI. Classification into normal and overweight categories using self0
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6 108 reported vs measured values was accurate in approximately 86% of women.
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8 109 The women included in these analyses were predominantly Caucasian (81%), had a partner at the
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10 110 time of study enrolment (96%), and had completed tertiary education (69%). Just over half were
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12 111 pregnant with their first child (Table 1). Approximately three quarters of women were enrolled
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14 112 in their 2nd trimester, and 86% of women came to all scheduled pre and postpartum visits. Pre0
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16 113 pregnancy BMI varied; almost two thirds were of normal BMI, 4% were underweight, 21% were
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18 114 overweight and 1% were obese.
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21 115 In this group of 1541 women, 761 (49%) exceeded Health Canada's guidelines for total GWG,
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23 116 while 272 (18%) gained less weight than recommended. Approximately 7% of women who
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25 117 were categorized as overweight or obese when entering pregnancy exceeded the guidelines,
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27 118 while 28% and 4% of underweight and normal weight women exceeded the guidelines. Weight
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29 119 gain lower than recommended was observed in 17% of underweight women, 22% of normal
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31 120 weight women, and 6% and 14% of overweight and obese women respectively. There was some
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33 121 evidence of weight loss, particularly in women who had entered pregnancy with a BMI that
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35 122 categorized them as obese.
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38 123 Within each prepregnancy BMI category, there was wide variation in total GWG (Figure 2). In
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40 124 the under0and normal weight groups, 9% and 1% exceeded the upper guideline limit by 50<1
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42 125 kg, while 3% exceeded by at least 1 kg in both groups. In the overweight and obese categories,
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44 126 19% and 24% of women, respectively, exceeded the upper guideline limit by 50l kg. Gains
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46 127 between >1 and <15 kg over the upper limit were observed in approximately 12% in each of the
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48 128 two groups while gains >15 kg above the upper limit were observed in 4% and 5% of women in
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51 129 the overweight and obese categories respectively. The proportions of SGA infants of women
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4 130 who were in the under, met and above GWG categories were 16.2%, 9.5% and 7.4%,
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6 131 respectively ($P = 0.004$). The proportions of LGA infants of women who were in the under, met
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8 132 and above GWG categories were 2.5%, 3.8%, 9.9%, respectively ($P < 0.001$).

9
10 133 The proportions of women who exceeded the recommended average weekly rate of GWG in the
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12 134 2nd and 3rd trimesters were higher in the overweight (88%) and obese (80%) groups than in the
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14 135 normal (60%) and underweight (35%) groups (Figure 3). The proportions of women who gained
15
16 136 weight at a rate that was more than double the upper recommended limits were 3%, 30% and
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18 137 40% of normal, overweight and obese women respectively.

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20 138 For normal weight and overweight groups, median weight gain exceeded the upper range of their
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22 139 respective guideline by approximately 30 weeks and 20 weeks of gestation respectively (Figure
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24 140 4). Over half of the women in the obese group had gained more weight than the recommended
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26 141 upper range by 18 weeks of gestation. In all BMI groups, weight gain continued to rise until the
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28 142 end of pregnancy.

29 143 Discussion

30 144 Main findings

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32 145 In this group of women from Alberta, Canada, adherence to Health Canada's revised GWG
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34 146 guidelines was low. Excess GWG was most marked among women with pre-pregnancy BMIs in
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36 147 the overweight and obese categories, although 40% of those who entered pregnancy with a
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38 148 normal BMI also experienced excessive GWG. **Women varied** in the extent to which ~~women~~
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40 149 they exceeded the guidelines with 16% of those overweight or obese pre-pregnancy exceeding
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42 150 their respective guidelines by more than 10 kg. **In addition**, GWG trajectories for women in the
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44 151 overweight and normal weight categories were very similar. The extent to which these
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46 152 similarities reflect physiological effects, psychosocial/behavioural effects or a combination of

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4 153 these should be topics for future research. Finally, we observed that over half of women in the
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6 154 overweight or obese group exceeded their respective guidelines by ~ 2 weeks gestation.

7 8 155 Explanation and comparison with other studies

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10 156 Our estimates are broadly consistent with those reported by recent studies in the USA and other
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12 157 Western countries where GWG is measured routinely^{4,12,16018} and highlights the universality of
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14 158 this issue across many countries and health care systems. Of note are the findings from a very
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16 159 recent study of GWG in normal weight women with low risk pregnancies, across seven countries
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18 160 worldwide, in which the average GWG was 13.7 kg, which is consistent with our results and the
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20 161 IOM recommendations.¹⁹

21
22 162 The magnitude of excessive weight gain and the fact that 4% of women in the obese category
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24 163 appeared to lose weight, suggests that weight management in pregnancy is a challenging and
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26 164 complex issue for women and healthcare providers to address.²⁰ Women who gained in excess
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28 165 of the guidelines were more likely to have a LGA baby which corroborates findings from other
29
30 166 research.²¹⁰²⁴ LGA pregnancies are more likely to result in delivery complications including:
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32 167 cesarean section, neonatal hypoglycemia or shoulder dystocia,²⁵ in addition to increased risk of
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34 168 overweight in childhood.²⁶⁰²⁸ Similarly, we also observed that relatively high proportions of
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36 169 underweight and normal weight women gained less weight than recommended and this was
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38 170 associated with increased risk of an SGA infant. It is not known if the risks or the consequences
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40 171 of inadequate weight gain during pregnancy differ by prepregnancy BMI. It is possible that
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42 172 there were clinical explanations for some of the excessive or inadequate GWG observed in this
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44 173 study; however as an observational study it was not an objective to explore clinical
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46 174 underpinnings and more research in this area is warranted.

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4 175 Approximately one third of women with a pre-pregnancy BMI in the overweight or obese
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6 176 categories had an average weekly rate of GWG in the 2nd and 3rd trimesters that was more than
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8 177 double the upper limit of the recommended rates. Rapid rates of weight gain are well
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10 178 documented during the 2nd to 3rd trimesters^{29,30}, although factors contributing to the markedly
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12 179 high rates observed in our study are not well understood. The fact that the majority of women in
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14 180 the normal, overweight and obese categories exceeded the recommended weekly rates of weight
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16 181 gain suggests that rapid weight gain is not well-attended to by health care providers or women
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18 182 during this phase of pregnancy.
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21 183 Historically, a sigmoidal the pattern of GWG that has been most commonly described is
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23 184 sigmoidal, accelerating between the 2nd and 3rd trimesters and plateauing in late pregnancy^{6,31} as
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25 185 fetal growth slows slowing in the final weeks of gestation.³² More recent evidence, including
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27 186 from our own study, suggests that maternal weight in many women may continue to increase up
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29 187 until delivery.^{33,34} High rates of GWG in the 2nd and 3rd trimester have been associated with
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31 188 larger gains in maternal fat mass, higher birth weight and longer birth length.^{35,36}

36 189 Limitations

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39 190 A limitation of our study was that pre-pregnancy BMI was calculated using self-reported pre-
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41 191 pregnancy weight; however, further analyses suggested that the data were reasonable. BMI was
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43 192 calculated using measured height and weight for 528 participants who were recruited during the
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45 193 first trimester, where weight gain should be minimal. The accuracy of BMI using self-reported
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47 194 pre-pregnancy weights was 99% in the obese category and 86% in each of the normal and
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49 195 overweight categories. For the latter 2 categories, over 10% in each group belonged to the
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51 196 next higher weight category. The self-reported underweight group had the lowest accuracy
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53 197 (71%). Self-reported highest weight during pregnancy was missing in 307 women and for these

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4 198 women their measured weight in the third trimester was used as a substitute. Sensitivity analysis
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6 199 and simulation studies were carried out to investigate the implications of these procedures. [Since](#)
7
8 200 the proportion of those who exceeded both total and rate of weight gain increased in all pre0
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10 201 pregnancy BMI categories the results reported in our study appear to be conservative estimates
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12 202 of the true proportions of excessive GWG.
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15 203 Compared women of childbearing age in a representative nationwide survey of Canadians ³⁷, a
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17 204 greater proportion of women in our study had higher levels of education and household income.
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19 205 As APrON is a prospective cohort study it was not designed to be representative of all Canadian
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21 206 women of childbearing age. Research has shown that higher education is associated with better
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23 207 GWG guideline adherence ³⁸, it is likely that GWG adherence in the general Canadian
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25 208 population of childbearing women is worse than what we reported here.
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29 209 Conclusions

30
31 210 Overall, our findings in this group of highly educated women suggest that weight management in
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33 211 pregnancy is challenging and complex, and that the scope of the issue is likely to be much larger
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35 212 than reported here. Nonetheless, these observations reinforce Health Canada's recommendations⁷
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37 213 that GWG should be discussed with all pregnant women, irrespective of prepregnancy BMI
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39 214 category, and that messages may need to be tailored for women in different prepregnancy BMI
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41 215 categories. Our observations also suggest that these conversations need to be held early in
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43 216 pregnancy, at a time when it is more feasible to provide support that may mitigate the risk of
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45 217 excessive or inadequate weight gain. Consideration of the average weekly rate of GWG may be
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47 218 particularly important for healthcare providers. Rate of GWG reflects a woman's likely
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49 219 trajectory of total GWG and may provide a tool to identify and provide additional support for
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220 women at risk of not meeting the GWG guidelines. More research is needed to explore how to
221 address the issue of GWG, particularly in the context of the Canadian healthcare system.
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7
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18 230 team.
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4 231 Figure Legends

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6 232 Figure 1. Consort diagram for participants in the Alberta Pregnancy Outcomes and Nutrition
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8 233 (APrON) study who were included in the analyses of gestational weight gain.

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10 234
11
12 235 **Box 1.** Description of the ranges of total and weekly rate of GWG according to Health Canada's
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14 236 recommendations by pre-pregnancy BMI category,

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16 237
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18 238 Figure 2. Histograms of total gestational weight gain (kg) by pre-pregnancy BMI category
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20 239 among women in the Alberta Pregnancy Outcomes and Nutrition (APrON) cohort. Total weight
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22 240 gain is shown along the x-axis in 2 kg blocks. The blue ticks on the x-axis indicate the lower and
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24 241 upper range recommended for total weight gain according to Health Canada's gestational weight
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26 242 gain guidelines and within the indicated pre-pregnancy body mass index category. The y-axis
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28 243 shows the proportion of women who gained that amount of total weight in pregnancy.

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30 244
31
32 245 Figure 3. Histograms of the weekly rate of gestational weight gain (kg/week) between the 2nd
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34 246 and 3rd trimesters of pregnancy by pre-pregnancy BMI category among women in the Alberta
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36 247 Pregnancy Outcomes and Nutrition (APrON) cohort. The rate of weight gain is shown along the
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38 248 x-axis in 5 kg/week blocks. The blue ticks on the x-axis indicate the recommended lower and
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40 249 upper range for weekly rate of weight gain, according to Health Canada's gestational weight gain
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42 250 guidelines and within the indicated pre-pregnancy body mass index category. The y-axis shows
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44 251 the proportion of women with a weekly rate of weight gain indicated.

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4 253 Figure 4. Box plots of the median and interquartile range of weight gained at each measurement
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6 254 time point according to pre0pregnancy body mass index category. Women were included in 2 or
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8 255 3 boxes each according to how many study visits they attended. The purple line and dashed
9
10 256 orange lines represent Health Canada’s gestational average and upper and lower ranges for total
11
12 257 weight gain for women within the specified pre0pregnancy body mass index category. The green
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14 258 line in the box plots for the overweight and obese women represents Health Canada’s average
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16 259 recommended weight gain for women with a normal pre0pregnancy body mass index. The red
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18 260 dots in each box indicate the median gestational age of women who contributed to that box. The
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20 261 box plot for the underweight pre0pregnancy BMI category underweight is not shown because of
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22 262 the small sample size (n=58).
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264 Table 1: Socio-demographic characteristics of women enrolled in the Alberta Pregnancy Outcomes
 265 and Nutrition (APrON) study according to their pre-pregnancy BMI

Characteristic n (%)	Total 1541	Underweight 58 (3.8)	Normal Weight 994 (64.5)	Overweight 328 (21.3)	Obese 161(10.4)	p0value of χ^2 test
			mean \pm SD			
Pre0pregnancy BMI (kg/m ²)	1541	17.7 \pm 0.9	21.8 \pm 1.7	27.1 \pm 1.4	34.5 \pm 4.2	
Height, cm	1541	167.2 \pm 6.9	165.6 \pm 6.4	166.1 \pm 6.2	165.0 \pm 7.7	
Pre0pregnancy weight, kg	1541	49.5 \pm 5.1	59.9 \pm 6.5	74.8 \pm 7.0	94.0 \pm 13.6	
Gestational Weight Gain, kg	1541	16.9 \pm 6.8	15.5 \pm 5.3	15.2 \pm 6.0	12.3 \pm 7.8	
Age, years	1519	28.8 \pm 4.1	31.2 \pm 4.3	31.8 \pm 4.4	31.2 \pm 4.4	
			n(%)			
Parity						χ^2 77
0	827 (53.6)	30 (3.6)	563 (68.1)	155 (18.7)	79 (9.6)	
1	539 (35)	18 (3.3)	333 (61.8)	128 (23.7)	60 (11.1)	
\geq 2	151 (9.7)	5 (3.3)	87 (57.6)	42 (27.8)	17 (11.3)	
Missing	24 (1.7)					
Marital status						χ^2 115
Married and Commonlaw	1460 (94.8)	49 (3.4)	948 (64.9)	315 (21.6)	148 (10.1)	
Divorced, Separated, Single	59 (3.8)	5 (8.5)	37 (62.7)	9 (15.3)	8 (13.6)	
Missing	22 (1.4)					
Ethnicity						χ^2 2
Asian	176 (11.4)	8 (4.5)	133 (75.6)	28 (15.9)	7 (4)	
Caucasian	1241 (80.5)	38 (3.1)	794 (64)	275 (22.2)	134 (10.8)	
Other*	94 (6.1)	7 (7.4)	54 (57.4)	19 (20.2)	14 (14.9)	
Missing	30 (2)					
Family income, \$ (Cdn)						χ^2 152
less than \$7000	325 (21.1)	16 (4.9)	200 (61.5)	68 (20.9)	41 (12.6)	
\$7000 or more	1178 (76.4)	36 (3.1)	774 (65.7)	253 (21.5)	115 (9.8)	
Missing	38 (2.4)					
Maternal education						$<$ χ^2 1
Completed high school diploma or lower	164 (10.6)	9 (5.5)	92 (56.1)	31 (18.9)	32 (19.5)	
Completed trade, technical	286 (18.6)	8 (2.8)	162 (56.6)	77 (26.9)	39 (13.6)	
Completed University	704 (45.7)	23 (3.3)	465 (66.1)	156 (22.2)	60 (8.5)	
Completed postgraduate	354 (23)	12 (3.4)	262 (74)	56 (15.8)	24 (6.8)	
Missing	33 (2.1)					

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266 *Other includes Arab, Black, Jamaican and Latin American.

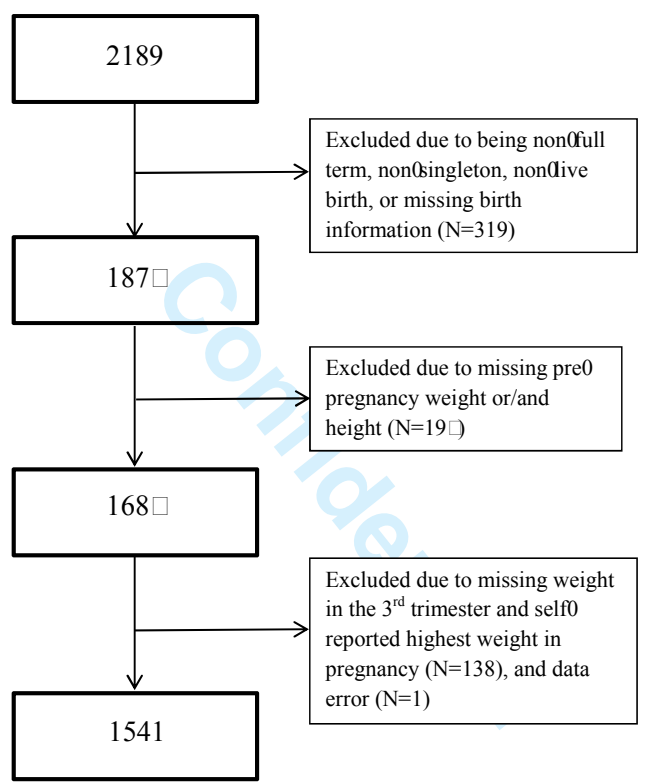
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Figure 1

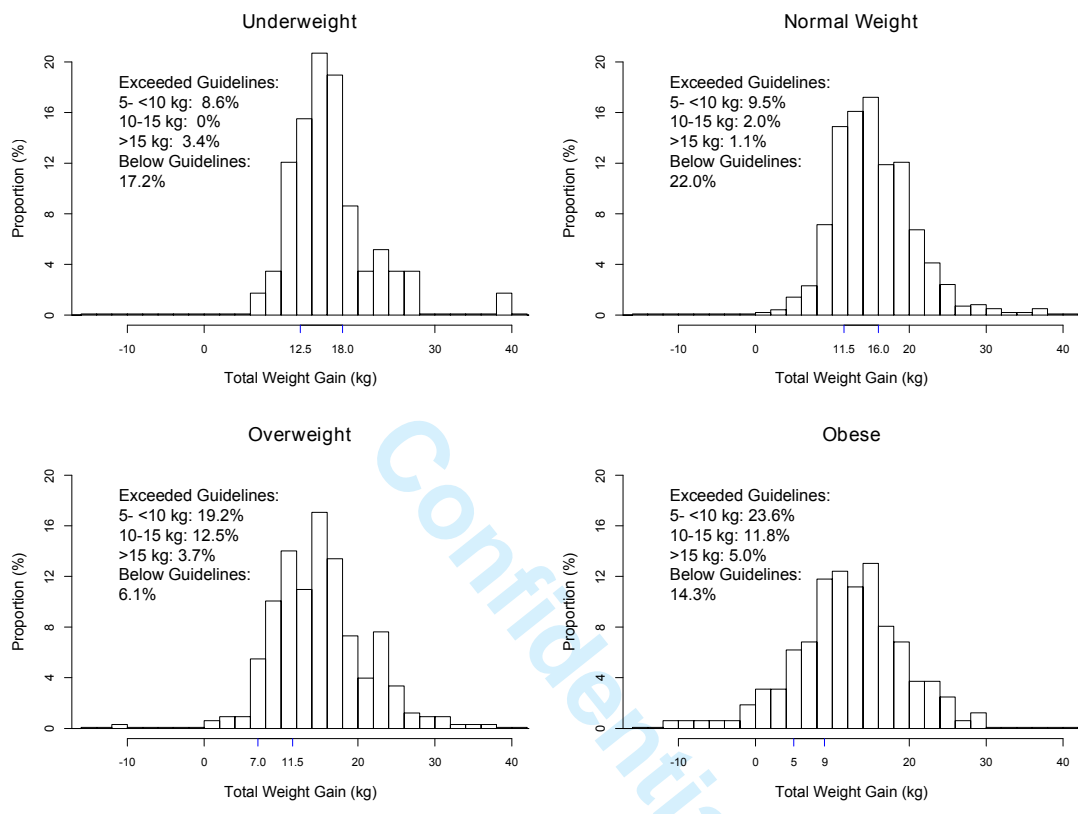


Box 1

Pre-pregnancy BMI	Total GWG	Rate GWG
Underweight:	12.50l8kg	□440□58kg/week
Normal weight:	11.50l6kg	□350□5kg/week
Overweight:	70l1.5kg	□230□33kg/week
Obese:	509kg	□170□27kg/week

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Figure 2



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Figure 3

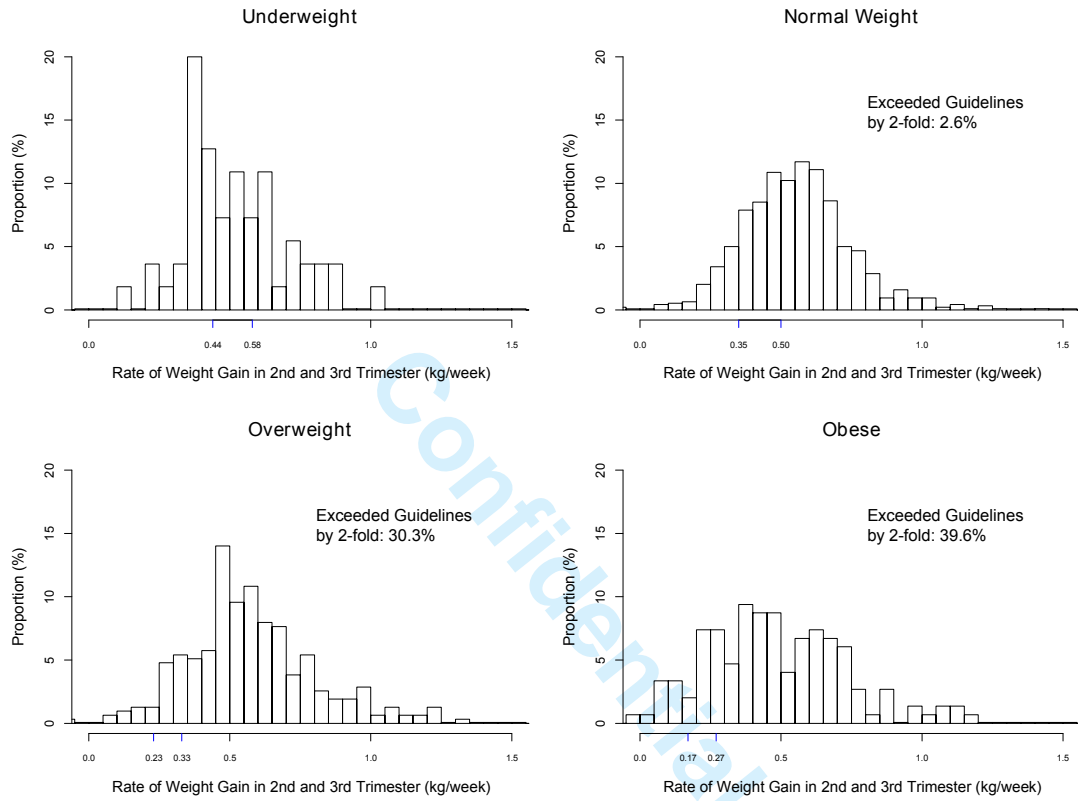
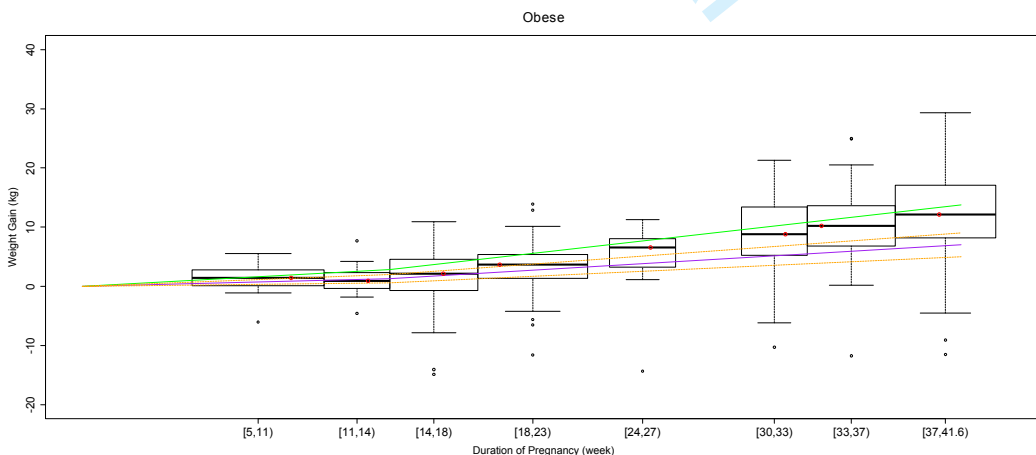
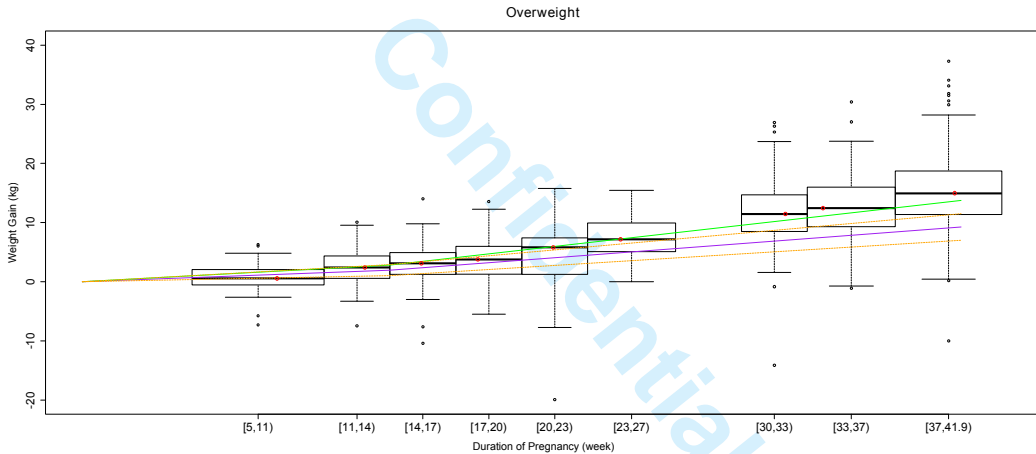
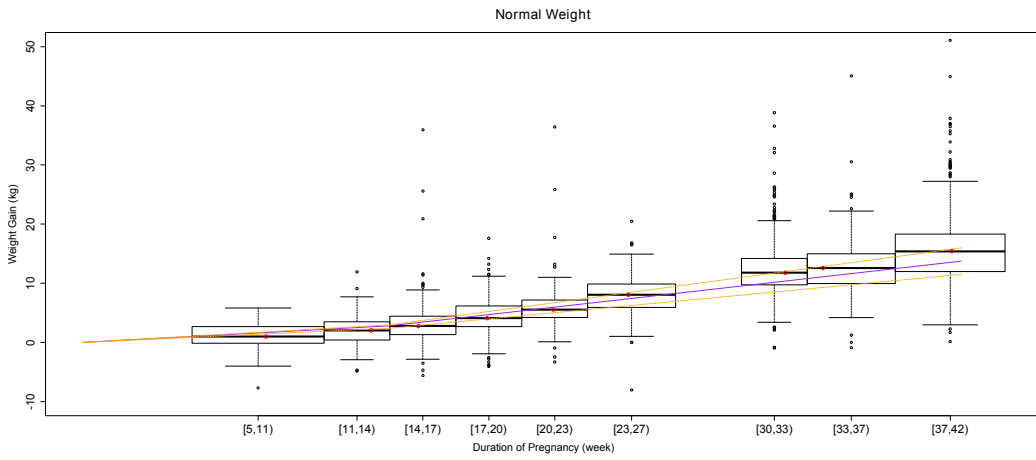


Figure 4

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Appendix 1 – completed STROBE checklist for reporting cohort studies

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cohort studies

Section/ Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	4
		(b) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4/5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4
Bias	9	Describe any efforts to address potential sources of bias	6
Study size	10	Explain how the study size was arrived at	6 and figure 1
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5/6

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5/6
		(b) Describe any methods used to examine subgroups and interactions	5/6
		(c) Explain how missing data were addressed	5/6
		(d) If applicable, explain how loss to follow-up was addressed	5/6
		(e) Describe any sensitivity analyses	5/6
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6 and figure 1
		(b) Give reasons for non-participation at each stage	6 and figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7 and Table 1
		(b) Indicate number of participants with missing data for each variable of interest	Table 1
		(c) Summarise follow-up time (eg, average and total amount)	7
Outcome data	15*	Report numbers of outcome events or summary measures over time	7/8
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8
		(b) Report category boundaries when continuous variables were categorized	7 and Box 1
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	7/8
Discussion			

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Key results	18	Summarise key results with reference to study objectives	8/9
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

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*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.