A telehealth lifestyle intervention to reduce excess gestational weight gain in pregnant women with overweight or obesity (GLOW): a randomised, parallel-group, controlled trial

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See **Comment** page 459

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Summary

Background Excess gestational weight gain (GWG) among women with overweight or obesity synergistically increases their already elevated risk of having gestational diabetes, a caesarean delivery, a large for gestational age infant, and post-partum weight retention, and increases their child's risk of obesity. We investigated whether a primarily telehealth lifestyle intervention reduced excess GWG among women with overweight or obesity.

Methods We did a randomised controlled trial in five antenatal clinics of Kaiser Permanente; Oakland, San Leandro, Walnut Creek, Fremont, and Santa Clara, CA, USA. Women at 8–15 weeks' gestation with singletons, pre-pregnancy BMI 25·0–40·0 kg/m², and aged 18 years or older were randomly assigned (1:1) to receive the telehealth lifestyle intervention or usual antenatal care. Randomisation was adaptively balanced for age, BMI, and race and ethnicity. Data collectors and investigators were masked to group assignments. The core lifestyle intervention consisted of two in-person and 11 telephone sessions on behavioural strategies to improve weight, diet, and physical activity, and stress management to help women meet a trial goal of gaining at the lower limit of the Institute of Medicine (IOM) guidelines range for total GWG: 7 kg for women with overweight and 5 kg for women with obesity. Usual antenatal care included an antenatal visit at 7–10 weeks' gestation, an additional seven antenatal visits, on average, and periodic health education newsletters, including the IOM GWG guidelines and information on healthy eating and physical activity in pregnancy. The primary outcome was weekly rate of GWG expressed as excess GWG, per Institute of Medicine guidelines and mean assessed in the intention-to-treat population. The trial is registered at ClinicalTrials.gov, NCT02130232.

Findings Between March 24, 2014, and Sept 26, 2017, 5329 women were assessed for eligibility and 200 were randomly assigned to the lifestyle intervention group and 198 to the usual care group. Analyses included 199 women in the lifestyle intervention group (one lost to follow-up) and 195 in the usual care group (three lost to follow-up). 96 (48%) women in the lifestyle intervention group and 134 (69%) women in the usual care group exceeded Institute of Medicine guidelines for rate of GWG per week (relative risk 0·70, 95% CI 0·59 to 0·83). Compared with usual care, women in the lifestyle intervention had reduced weekly rate of GWG (mean 0·26 kg per week [SD 0·15] *vs* 0·32 kg per week [0·13]; mean between-group difference –0·07 kg per week, 95% CI –0·09 to –0·04). No between-group differences in perinatal complications were observed.

Interpretation Our evidence-based programme showed that health-care delivery systems could further adapt to meet the needs of their clinical settings to prevent excess GWG and improve healthy behaviours and markers of insulin resistance among women with overweight or obesity by using telehealth lifestyle interventions.

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Introduction

There is a growing global epidemic of obesity and excessive gestational weight gain (GWG) in pregnancy. In the USA, 60% of women enter pregnancy with overweight or obesity,[1] whereas it is 30% in Europe and 10% in Asia.[2] In the USA, approximately 64% of pregnant women with overweight or obesity exceed the Institute of Medicine guidelines for GWG.[1,3] A 2018 report showed that 51% of pregnant women in Europe and 37% of pregnant women in Asia exceeded the Institute of Medicine guidelines for GWG, regardless of their BMI.[2]

Observational studies[4,5] show that excess GWG among women with overweight or obesity synergistically increases their elevated risk of having gestational diabetes, a caesarean delivery, a large for gestational age infant, and post-partum weight retention, and increases their child's risk of obesity. Thus, improving GWG among women with overweight or obesity is a public health priority and a

Research in context

Evidence before this study

Observational studies strongly suggest that excess gestational weight gain (GWG) is associated with increased risk of perinatal complications; however, lifestyle interventions among women with overweight or obesity were found ineffective in reducing excess GWG or perinatal complications, although these studies had relatively small sample sizes. We searched Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and PubMed for literature published from Jan 1, 2008, to Dec 31, 2019, in English language, with the search terms "pregnancy and weight gain," "overweight or obesity," and "lifestyle intervention". All the randomised controlled trials aimed at reducing GWG among women with overweight or obesity that we reviewed strongly suggested the need for novel lifestyle interventions to show whether it was possible to reduce excess GWG in this population. In the past 5 years, after starting our trial, intensive in-person lifestyle interventions, analysed individually and in meta-analysis, have been effective in reducing excess GWG among women with overweight or obesity, although they were not effective in reducing perinatal complications. Intensive interventions, requiring in-person counselling with multiple visits to clinics, might not be feasible for many women, can decrease treatment efficacy, and could be difficult to implement in health-care delivery settings.

Added value of this study

The GLOW trial compared a theory-based behavioural intervention, delivered primarily by telehealth, with usual antenatal care for women with overweight or obesity with the goal to reduce excess GWG. Compared with usual care, the intervention substantially reduced the proportion of women exceeding the Institute of Medicine guidelines for weekly rate of GWG. The intervention also reduced total caloric intake, proportion of calories from saturated fat, sedentary behaviours, markers of insulin resistance, and serum leptin concentration. These favourable changes were not reported in the previous trials or trials published after the start of our trial. However, in our trial no between-group differences in perinatal complications were observed, consistent with most trials aimed at reducing GWG.

Implications of all the available evidence

The GLOW intervention is an evidence-based programme that can be adapted and adopted by health-care delivery systems to prevent excess GWG and improve healthy behaviours and markers of insulin resistance among women with overweight or obesity. Although larger trials with longer follow-up periods are needed to assess the effect of reduced GWG on perinatal and long-term outcomes, obesity prevention efforts in women of reproductive age are urgently needed to possibly reduce the adverse health consequences associated with obesity.

serious concern for health-care delivery systems. Pregnancy is a unique time when women are in frequent contact with the health-care system and are often motivated to make lifestyle changes out of concern for their infants. However, it is only recently that intensive behavioural lifestyle interventions with in-person counselling have been effective in reducing excess GWG among women with overweight or obesity.[6,7] Intensive interventions, requiring in-person counselling with multiple visits to clinic might not be feasible for many women, can decrease treatment efficacy, and could be difficult to implement in health-care delivery settings.[8] Telehealth is increasingly used in such settings to increase efficiency and has been shown to be effective in improving perinatal outcomes.[9]

The aim of the GestationaL Weight Gain and Optimal Wellness (GLOW) randomised controlled trial was to reduce excess GWG through a behavioural lifestyle intervention adapted from the Diabetes Prevention Program (DPP)[10] and delivered primarily by telehealth to be feasible in health-care delivery settings.

Methods

Study design and participants

We did a two-arm, parallel-group, randomised controlled trial in antenatal clinics in five medical centres (Oakland, San Leandro, Walnut Creek, Fremont, and Santa Clara) of Kaiser Permanente Northern California (KPNC), CA,USA, which is a large, pre-paid, integrated health system serving over 4 million members broadly representative of the underlying geographical area.[11] Pregnant women were first identified in the electronic health record system using the following eligibility criteria: pre-pregnancy BMI between 25·0 kg/m² and 40·0 kg/m², aged 18 years or older, and a singleton pregnancy. Inclusion in the trial was further assessed by review of electronic health records, approval from medical providers to contact each woman, and a recruitment screening telephone call. Exclusion criteria included fertility-assisted pregnancy; bed rest; diabetes diagnosis; current uncontrolled hypertension; thyroid disease diagnosed in last 30 days; history of cardiovascular, cancer, lung or serious gastrointestinal disease; history of eating disorder or bariatric surgery; serious mental illness; recent history of mood or anxiety disorder; drug or alcohol use disorder; more than 13 weeks' gestation; and gestational diabetes diagnosis (appendix p 1).[11] All trial participants provided written informed consent. GLOW was approved by the Kaiser Foundation Research Institute Human Subjects Committee.

See Online for appendix

Randomisation and masking

Eligible women who attended the baseline clinic visit and provided informed consent were randomly assigned to either usual antenatal care or the lifestyle intervention

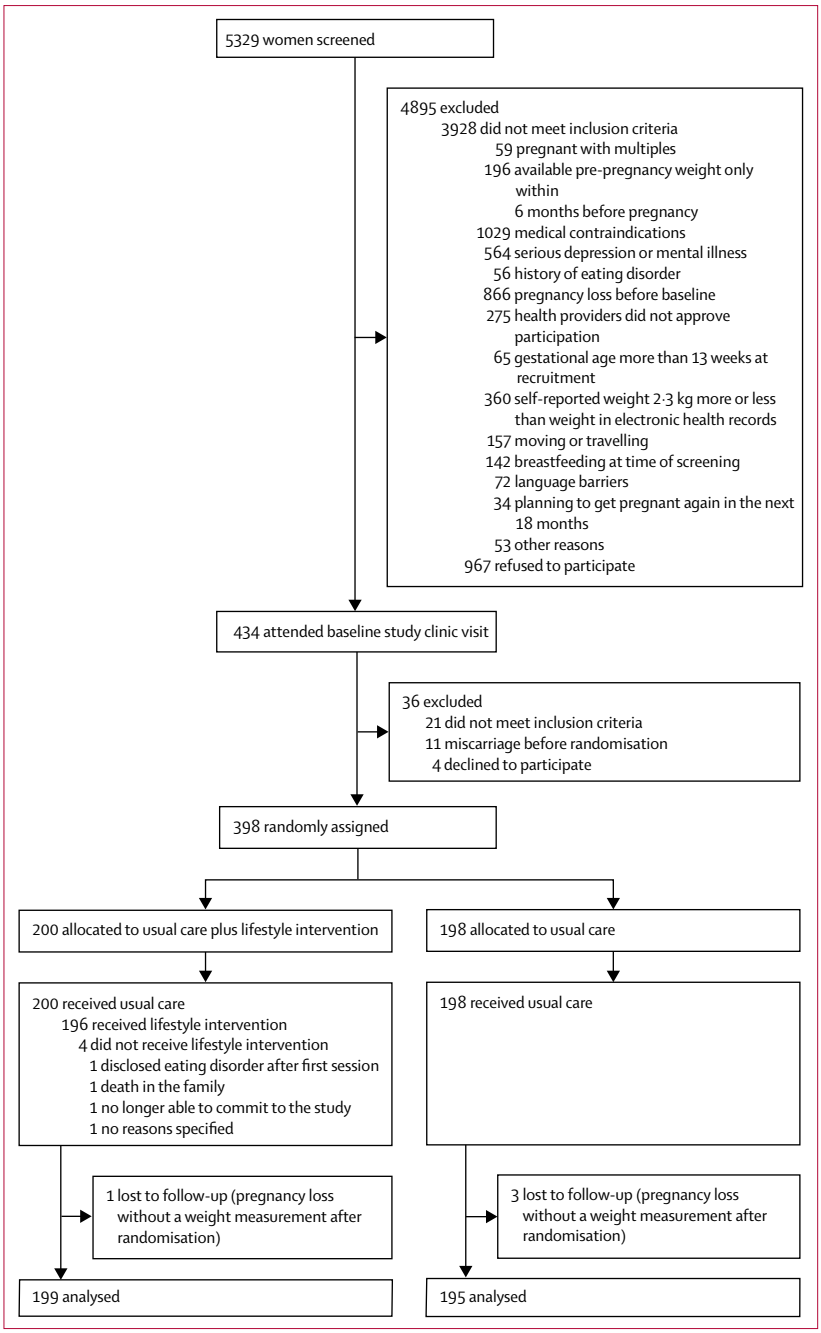

Figure: **Trial profile**

plus usual antenatal care by an unmasked project manager. An adaptive randomisation procedure[12] was used to ensure that equal numbers of women were assigned to each study group and that the two groups remained balanced within each medical centre on levels of key characteristics: age (aged <30 and ≥30 years), pre-pregnancy BMI (25·0–29·9 kg/m², 30·0–34·9 kg/m², and 35·0–40·0 kg/m²), and race and ethnicity (Asian or Pacific Islander; black; Hispanic; white; and multiracial, other, or unknown). Data collectors, study investigators, the biostatistician, and analysts were masked to group assignment.

Procedures

Women randomly assigned to the usual care received standard KPNC antenatal medical care, which included an antenatal visit at 7–10 weeks' gestation, an additional seven antenatal visits on average, and periodic health education newsletters, including the Institute of Medicine GWG guidelines and information on healthy eating and physical activity in pregnancy. Medical staff unaware of group assignment weighed women at each antenatal visit. In addition to standard KPNC antenatal care, women in the usual care group received four study newsletters that focused on women's health and safety during pregnancy without addressing GWG.

In addition to usual antenatal care, women randomly assigned to the intervention received a lifestyle intervention adapted from the DPP[10] and primarily delivered by telehealth, designed to be feasible among pregnant women and adoptable by health-care delivery settings. Intervention structure and content have been described previously.[11] Briefly, the intervention targeted behaviour changes for weight management (eg, daily self-weighing), healthy eating (eg, setting goals for eating healthy foods in appropriate portion sizes, total caloric intake, and calories from fat),[10] physical activity (eg, doing 150 min per week of moderate-intensity to vigorous-intensity physical activity), and stress management to help women meet a trial goal of gaining at the lower limit of the Institute of Medicine guidelines range for total GWG: 7 kg for women with overweight and 5 kg for women with obesity.[11] The intervention was delivered by dietitians using motivational interviewing techniques[13] and a step-wise, phased approach to behaviour change based on social cognitive theory[14] and the transtheoretical model.[15] The core of the intervention, which started soon after randomisation, included 13 weekly individual sessions. The first and last sessions were in person and the remaining 11 were delivered by telephone. At the initial in-person session women were advised of their GWG goal for the end of pregnancy. The trial goal for GWG was defined as total GWG that did not exceed the lower limit of the Institute of Medicine guidelines[3] range: no more than 7 kg for women with pre-pregnancy BMI 25·0–29·9 kg/m² or 5 kg for women with pre-pregnancy BMI 30·0 kg/m² or higher. Women were provided a printed workbook to discuss at each session; a scale to encourage self-weighing; and a personalised electronic or paper-based graph to track their weight. Participants and coaches reviewed weight change in relation to the GWG goal at each intervention session. Following the 13 core sessions, participants were offered, but were not required to complete, every other week maintenance sessions by telephone until 38 weeks' gestation.[11] Dietitians tracked the duration of intervention sessions.

Data were collected by trained research staff from electronic health records and at two study clinic visits: at the baseline visit, which was between 8 and 15 weeks' gestation (median 12 weeks [IQR 11–13]), and at the second visit, which was between 29 and 38 weeks' gestation (32 weeks [IQR 31–33]).

Pre-pregnancy weight was abstracted from electronic health records and defined as the latest pre-pregnancy weight measured by KPNC medical staff within 6 months before the last menstrual period; or, for women without a measured pre-pregnancy weight, as the earliest pregnancy weight measured by KPNC medical staff before 10 weeks' gestation. Pre-pregnancy weight from electronic health records and height measured at the baseline study clinic visit were used to calculate pre-pregnancy BMI. Overweight was defined as a pre-pregnancy BMI of 25·0–29·9 kg/m² and obesity as 30·0–40·0 kg/m². Women's weight and height were measured according to a rigorous protocol[11] at study clinic visits along with demographic characteristics. Last menstrual period and gestational age were confirmed by ultrasounds done before the baseline study clinic visit and abstracted from electronic health records.

Within 1 week after both study clinic visits, 24-h dietary recalls were done on three randomly selected days and physical activity was assessed for 1 week by an ActiGraph wGT3X-BT accelerometer (ActiGraph, Pensacola, FL, USA; appendix pp 1–2).[11]

Women's blood samples after fasting at least 8 h were collected at both study clinic visits[11] to measure glucose, insulin, adiponectin, leptin, free fatty acids, total cholesterol, triglycerides, HDL, LDL, and VLDL. Homoeostatic model assessment was calculated and used as a marker of insulin resistance.[16] Cord blood samples were collected in a subsample to measure glucose, insulin, C-peptide, free fatty acids, and leptin. All blood samples were analysed at the University of Washington's Northwest Lipid Metabolism and Diabetes Research Laboratories, Seattle, WA, USA.

Outcomes

The primary outcome was weekly rate of GWG, expressed as excess GWG, per Institute of Medicine guidelines,[3] and mean. Mean weekly rate of GWG was calculated by total GWG (last measured pregnancy weight minus pre-pregnancy weight) by the number of weeks between ultrasound-confirmed last menstrual period date and the date of the last measured pregnancy weight. The Institute of Medicine's BMI-specific guidelines[3] for weekly rate of GWG include a range for weight gain during the first trimester (0·5–2·0 kg, regardless of BMI) along with BMI-specific ranges for weight gain per week during the second and third trimesters (0·23–0·33 kg for overweight and 0·17–0·33 kg for obesity). Exceeding the weekly rate of GWG according to Institute of Medicine guidelines was defined as being above the sum of the upper limit for the

	Intervention n=199	Usual care n=195	Combined n=394
Age, years			
20–29	54 (27%)	54 (28%)	108 (27%)
30–34	91 (46%)	81 (42%)	172 (44%)
35–42	54 (27%)	60 (31%)	114 (29%)
Mean (SD)	32·4 (4·1)	32·6 (4·3)	32·5 (4)
Race and ethnicity			
Asian	43 (22%)	38 (20%)	81 (21%)
White	64 (32%)	64 (33%)	128 (33%)
Hispanic	39 (20%)	39 (20%)	78 (20%)
African American	16 (8%)	16 (8%)	32 (8%)
Multiracial and other	37 (19%)	38 (20%)	75 (19%)
Pre-pregnancy BMI, kg/m²*			
25·0–29·9	131 (66%)	124 (64%)	255 (65%)
30·0–40·0	68 (34%)	71 (36%)	139 (35%)
Mean (SD)	29·3 (3·4)	29·5 (3·8)	29·4 (3·6)
Pre-pregnancy weight, kg*	77·7 (12·2)	78·7 (12·3)	78·2 (12·3)
Weight at baseline clinic visit, kg	77·6 (12·3)	78·8 (12·3)	78·2 (12·3)
Gestational weight gain up to baseline clinic visit, kg	–0·03 (2·6)	0·05 (2·5)	0·01 (2·6)
Gestational age at randomisation, weeks	14·2 (1·4)	14·4 (1·3)	14·3 (1·3)
Gestational age at last measured pregnancy weight, weeks	38·5 (3·7)	38·4 (3·4)	38·4 (3·5)
Time between last measured pregnancy weight and delivery, weeks	0·6 (0·8)	1·0 (2·6)	0·8 (1·9)
Parity			
0	109 (55%)	99 (51%)	208 (53%)
1	68 (34%)	68 (35%)	136 (35%)
2+	21 (11%)	28 (14%)	49 (12%)
Missing	1 (1%)	0	1 (<1%)
Education			
High school graduated or less	10 (5%)	12 (6%)	22 (6%)
Some college	50 (25%)	36 (19%)	86 (22%)
College graduated or more	139 (70%)	147 (75%)	286 (73%)
Gestational age at last measured weight, weeks			
13·6–34·9	10 (5%)	11 (6%)	21 (5%)
35–36·9	12 (6%)	18 (9%)	30 (8%)
37–42·4	177 (89%)	166 (85%)	343 (87%)
Time between last measured pregnancy weight and delivery, weeks†			
<1	150 (75%)	147 (75%)	297 (75%)
1 to <2	36 (18%)	35 (18%)	71 (18%)
2 to <3	7 (4%)	7 (4%)	14 (4%)
3 to <5	1 (1%)	1 (1%)	2 (1%)
5+	1 (1%)	4 (2%)	5 (1%)
Missing‡	4 (2%)	1 (1%)	5 (1%)
Infant sex			
Female	92 (46%)	102 (52%)	194 (49%)
Male	102 (51%)	92 (47%)	194 (49%)
Missing§	5 (3%)	1 (1%)	6 (2%)

Data are n (%) or mean (SD). *The latest pre-pregnancy weight measured within 6 months before the last menstrual period was used for 155 (78%) women in the intervention group and 151 (77%) in the usual care group; the earliest pregnancy weight measured before 10 weeks of gestation was used for 44 (22%) in the intervention group and 44 (23%) in the usual care group. †Delivery after 20 weeks' gestation. ‡Four missing due to pregnancy loss in the intervention group; one missing due to pregnancy loss in the usual care group. §Four missing due to pregnancy loss and one due to unknown sex in the intervention group; one missing due to pregnancy loss in the usual care.

Table 1: **Baseline characteristics**

first trimester (2·0 kg) + upper limit for the weekly rate (0·33 kg for overweight, 0·27 kg for obesity) × number of weeks in the second and third trimesters (ie, up until the last measured pregnancy weight). Being below the Institute of Medicine guidelines for weekly rate of GWG was defined as being below the sum of the lower limit for the first trimester (0·5 kg) × lower limit for the weekly rate (0·23 kg for overweight, 0·17 kg for obesity) × number of weeks in the second and third trimesters (ie, up until the last measured pregnancy weight). Meeting the recommendations was defined as being within the Institute of Medicine cutpoints.

Prespecified secondary GWG outcomes were total GWG, total GWG in excess of the Institute of Medicine guidelines for total GWG, rate of GWG per week between study clinic visits, and the proportion meeting the trial goal for GWG (lower limit of Institute of Medicine guidelines for total GWG). Other prespecified secondary outcomes were changes during pregnancy in total caloric intake, proportion of calories from total fat and saturated and unsaturated fat, physical activity (ie, objectively measured and estimated metabolic equivalent h per week, by intensity level, from self-report), and changes in serum concentrations of metabolic markers. Cord blood concentrations of metabolic markers were analysed in a subsample. Prespecified perinatal complications included birthweight centiles[17] (≥90th, ≥95th, ≤10th, and ≤5th), macrosomia (>4000 g), low birthweight (<2500 g), pregnancy loss, preterm delivery (<37 weeks), primary caesarean section, diagnoses of gestational hypertension, pre-eclampsia, and gestational diabetes (defined by Carpenter and Coustan criteria[18] or a fasting glucose value ≥5·3 mmol/L after a glucose value 1 h after a 50 g oral glucose challenge test ≥10·0 mmol/L).

Statistical analysis

Our target sample size was 400 participants, with 200 per group, which was estimated to provide a maximum (protective effect assumed) detectable relative risk (RR; intervention *vs* usual care) of exceeding the Institute of

	Intervention n=199	Usual care n=195	Between-group difference in means* (95% CI)	Relative risk* (95% CI)	p value
Exceeding IOM weekly rate of GWG	96 (48%)	134 (69%)	..	0·70 (0·59 to 0·83)	<0·0001
Meeting IOM weekly rate of GWG	65 (33%)	46 (24%)	..	1·38 (1·00 to 1·90)	0·049
Below IOM weekly rate of GWG	38 (19%)	15 (8%)	..	2·49 (1·44 to 4·31)	<0·0001
Weekly rate of gestational weight gain, kg/week					
Among all women	0·26 (0·15, n=199)	0·32 (0·13, n=195)	−0·07 (−0·09 to −0·04)	..	<0·0001
Among women with BMI 25·0 to 29·9 kg/m²	0·28 (0·14, n=131)	0·33 (0·13, n=124)	−0·05 (−0·08 to −0·02)	..	..
Among women with BMI 30·0 to 40·0 kg/m²	0·20 (0·15, n=68)	0·30 (0·14, n=71)	−0·09 (−0·14 to −0·04)	..	..
Exceeding IOM total GWG†	80 (41%)	128 (66%)	..	0·62 (0·51 to 0·76)	<0·0001
Meeting IOM total GWG†	69 (36%)	42 (22%)	..	1·66 (1·21 to 2·30)	0·0022
Below IOM total GWG†	45 (23%)	24 (12%)	..	1·84 (1·17 to 2·87)	0·0078
Total GWG, kg†					
Among all women	10·21 (5·63, n=194)	12·36 (5·28, n=194)	−2·19 (−3·26 to −1·12)	..	<0·0001
Among women with BMI 25·0 to 29·9 kg/m²	11·39 (5·13, n=126)	12·80 (5·02, n=123)	−1·42 (−2·68 to −0·17)	..	..
Among women with BMI 30·0 to 40·0 kg/m²	8·00 (5·90, n=68)	11·60 (5·66, n=71)	−3·54 (−5·51 to −1·57)	..	..
Rate of GWG between 8 to 15 and 29 to 38 weeks of gestation, kg per week‡					
Among all women	0·31 (0·18, n=178)	0·42 (0·16, n=186)	−0·11 (−0·15 to −0·08)	..	<0·0001
Among women with BMI 25·0 to 29·9 kg/m²	0·36 (0·16, n=118)	0·45 (0·16, n=117)	−0·08 (−0·12 to −0·04)	..	..
Among women with BMI 30·0 to 40·0 kg/m²	0·23 (0·17, n=60)	0·39 (0·16, n=69)	−0·17 (−0·23 to −0·11)	..	..
Met trial goal for total GWG†	47 (24%)	24 (12%)	..	1·94 (1·25 to 3·02)	0·0033

Data are n (%) or mean (SD, n), unless otherwise stated. Met the trial goal for GWG was defined as total GWG that did not exceed the lower limit of the IOM-recommended range: no more than 7 kg for women with pre-pregnancy BMI 25·0–29·9 kg/m² or 5 kg for women with pre-pregnancy BMI ≥30·0 kg/m². Pre-pregnancy BMI by group interaction for weekly rate of GWG p value was 0·24, total GWG p value was 0·15, and rate of GWG per week between 8–15 and 29–38 weeks of gestation p value was 0·012. GWG=gestational weight gain. IOM=Institute of Medicine. *Adjusted for age, race, ethnicity, pre-pregnancy BMI, medical centre, and pre-pregnancy weight (or weight at 8–15 weeks of gestation for rate of GWG between 8–15 and 29–38 weeks of gestation).†Analysis excluded five women in the intervention and one woman in usual care who had a pregnancy loss or stillbirth before 24 weeks' gestation. ‡Analysis excluded 21 women in the intervention and nine women in usual care who did not attend clinic visit at 32 weeks' gestation.

***Table 2*: GWG by randomised group assignment**

Medicine GWG guidelines of 0·75 (statistical power of 80%, significance level α of 0·05, two-sided test; expected proportion in the usual care group was 59%, given preliminary data). In addition, this sample size provided 80% statistical power to detect a between-group difference in mean weekly rate of GWG of at least 0·053 kg per week, assuming 10% attrition (significance level α of 0·05, two-sided test; expected SD of 0·18 kg/week given preliminary data).

All statistical analyses were done in the intention-to-treat population, which included all women for whom a pregnancy weight measured after randomisation was available (99%). Modified Poisson regression[19] was used to compare groups on dichotomous outcomes, such as the proportion of women exceeding Institute of Medicine guidelines for weekly rate of GWG and total GWG, providing point and interval estimates of RR. Multiple linear regression was used to provide point and interval estimates of the overall difference between usual care and intervention groups in mean weekly rate of GWG and total GWG, as well as to examine the differences in mean diet, physical activity, and metabolic markers. All analyses were adjusted for the variables used in the adaptive randomisation procedure,[20] as well as pre-pregnancy weight for GWG outcomes. Prespecified subgroup analyses of GWG with interaction tests for heterogeneity in group effect were done for pre-pregnancy BMI (overweight, obesity). For metabolic biomarkers, log transformations for normality were done when appropriate. Analysis results for these variables are presented on the original measurement scale via transformation of regression coefficients, providing point and interval estimates of the ratio of geometric means. Mediation analyses[21] were done to examine the proportion of the intervention's effect on changes in metabolic markers that was mediated by rate of GWG per week between the two study clinic visits (ie, between 8–15 and 29–38 weeks of gestation).

The trial was monitored by an independent data and safety monitoring board. The board met annually with the study investigators, received annual reports, and had the option to request additional reports due to unforeseen problems. All analyses were done using SAS (version 9.3). The trial is registered with ClinicalTrials.gov, NCT02130232.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between March 24, 2014, and Sept 26, 2017, 5329 women were assessed for eligibility, of whom 200 were randomly assigned to the intervention group and 198 to the usual care group (figure). Five (3%) women in the intervention group and four (2%) in the usual care group had a pregnancy loss after randomisation and before 23 weeks of gestation (p=0·76). A pregnancy weight measured after

	Intervention (n=199)	Usual care (n=195)	Between-group difference in means* (95% CI)	p value
Diet				
Total calories, kcal per day				
8 to 15 weeks' gestation	1798·7 (440·0)	1837·5 (408·8)	..	..
29 to 38 weeks' gestation	1848·9 (482·1)	1986·7 (461·2)	..	..
Change	50·2 (414·2)	149·2 (446·3)	−107·3 (−192·2 to −22·5)	0·013
Proportion of calories from total fat				
8 to 15 weeks' gestation	34·2% (5·6)	34·7 (5·4)	..	..
29 to 38 weeks' gestation	35·4% (7·0)	36·6 (5·5)	..	..
Change	1·1% (6·9)	1·9 (5·8)	−0·87 (−2·08 to 0·35)	0·16
Proportion of calories from saturated fat				
8 to 15 weeks' gestation	11·3% (2·8)	11·5 (2·6)	..	..
29 to 38 weeks' gestation	11·5% (3·1)	12·3 (2·6)	..	..
Change	0·2% (3·1)	0·8 (2·9)	−0·65 (−1·20 to −0·09)	0·022
Proportion of calories from unsaturated fat				
8 to 15 weeks' gestation	19·9% (3·6)	20·1 (3·5)	..	..
29 to 38 weeks' gestation	20·8% (4·5)	21·1 (4·0)	..	..
Change	0·9% (5·2)	1·0 (4·2)	−0·17 (−1·05 to 0·71)	0·71
Physical activity by accelerometer†				
Total activity, vector magnitude activity counts per min				
8 to 15 weeks' gestation	2569·1 (579·2)	2557·1 (561·6)	..	..
29 to 38 weeks' gestation	2576·2 (598·8)	2576·3 (529·4)	..	..
Change	7·2 (418·4)	19·3 (382·3)	−8·64 (−102 to 84·28)	0·86
Vigorous intensity activity, min per day‡				
8 to 15 weeks' gestation	2·7 (5·8)	2·4 (4·7)	..	..
29 to 38 weeks' gestation	1·5 (3·0)	1·5 (3·0)	..	..
Change	−1·2 (5·7)	−0·9 (4·3)	−0·07 (−0·77 to 0·64)	0·85
Moderate intensity activity, min per day‡				
8 to 15 weeks' gestation	53·3 (65·1)	65·0 (88·9)	..	..
29 to 38 weeks' gestation	47·7 (73·9)	49·9 (70·0)	..	..
Change	−5·6 (84·3)	−15·1 (94·6)	1·27 (−15·8 to 18·37)	0·88
Self-reported physical activity				
Total activity, MET h per week				
8 to 15 weeks' gestation	115·2 (74·0)	115·2 (74·0)	..	..
29 to 38 weeks' gestation	106·4 (70·7)	110·7 (76·8)	..	..
Change	−8·8 (63·0)	−7·4 (64·3)	−2·18 (−13·8 to 9·45)	0·71
Vigorous intensity activity, MET h per week				
8 to 15 weeks' gestation	2·3 (4·1)	2·0 (3·9)	..	..
29 to 38 weeks' gestation	1·0 (2·1)	1·0 (2·7)	..	..
Change	−1·3 (3·5)	−1·0 (3·9)	−0·14 (−0·61 to 0·33)	0·56

(Table 3 continues on next page)

	Intervention	Usual care	Between-group difference in means* (95% CI)	p value
(Continued from previous page)				
Moderate intensity activity, MET h per week				
8 to 15 weeks' gestation	60·3 (50·1)	61·4 (53·0)	..	..
29 to 38 weeks' gestation	54·1 (46·4)	54·8 (47·1)	..	..
Change	−6·2 (47·7)	−6·6 (41·3)	0·09 (−7·86 to 8·05)	0·98
Sedentary behaviour, MET h per week				
8 to 15 weeks' gestation	52·5 (27·2)	51·3 (27·4)	..	..
29 to 38 weeks' gestation	48·2 (24·9)	52·8 (27·3)	..	..
Change	−4·4 (22·6)	1·5 (24·5)	−4·78 (−9·12 to −0·44)	0·031
Metabolic markers				
Fasting glucose, mmol/L§				
8 to 15 weeks' gestation	4·4 (0·6)	4·3 (0·6)	..	..
29 to 38 weeks' gestation	4·2 (0·7)	4·3 (0·7)	..	..
Change	−0·1 (0·6)	−0·1 (0·6)	−0·03 (−0·16 to 0·09)	0·58
Fasting insulin, pmol/L§				
8 to 15 weeks' gestation	37·9 (24·7)	40·6 (21·3)	..	..
29 to 38 weeks' gestation	55·1 (32·2)	67·1 (39·8)	..	..
Change	17·2 (23·2)	26·5 (33·1)	−8·53 (−14·8 to −2·28)	0·076
Fasting HOMA-IR				
8 to 15 weeks' gestation	1·3 (0·9)	1·3 (0·8)	..	..
29 to 38 weeks' gestation	1·8 (1·2)	2·2 (1·5)	..	..
Change	0·5 (0·9)	0·9 (1·3)	−0·30 (−0·53 to −0·06)	0·015
Leptin, nmol/L				
8 to 15 weeks' gestation	4·0 (1·9)	4·3 (1·9)	..	..
29 to 38 weeks' gestation	4·5 (2·2)	5·2 (2·4)	..	..
Change	0·4 (1·3)	1·0 (1·5)	−0·51 (−0·81 to −0·22)	0·0076
Adiponectin, ng/mL				
8 to 15 weeks' gestation	9923·4 (4051·4)	9506·1 (3966·0)	..	..
29 to 38 weeks' gestation	8655·2 (3882·3)	8267·8 (3442·0)	..	..
Change	−1268·2 (2386·4)	−1238·3 (2656·2)	108·2 (−370 to 586·0)	0·66
Cholesterol, mmol/L				
8 to 15 weeks' gestation	4·7 (1·0)	4·7 (1·0)	..	..
29 to 38 weeks' gestation	6·0 (1·4)	5·9 (1·5)	..	..
Change	1·3 (0·9)	1·3 (1·0)	0·08 (−0·12 to 0·29)	0·44
LDL, mmol/L¶				
8 to 15 weeks' gestation	2·5 (0·8)	2·5 (0·9)	..	..
29 to 38 weeks' gestation	3·4 (1·2)	3·2 (1·3)	..	..
Change	0·9 (0·9)	0·8 (0·9)	0·11 (−0·08 to 0·30)	0·27
HDL, mmol/L				
8 to 15 weeks' gestation	1·6 (0·4)	1·7 (0·4)	..	..
29 to 38 weeks' gestation	1·7 (0·5)	1·7 (0·5)	..	..
Change	0·1 (0·3)	0·1 (0·3)	−0·02 (−0·09 to 0·04)	0·49

(Table 3 continues on next page)

randomisation was available in electronic health records for four of five women with a pregnancy loss in the intervention group and for one of four women with a pregnancy loss in the usual care group. Therefore, 199 (>99%) women in the intervention group and 195 (99%) in the usual care group were included in analyses of weekly rate of GWG, the primary outcome measure. The intervention was started at a median of 14·3 gestational weeks (IQR 13·3–15·1). The treatment groups were similar and well balanced with respect to demographic and other baseline characteristics (table 1). There were also no between-group differences in key characteristics such as age, race or ethnicity, pre-pregnancy BMI, and pre-pregnancy weight in the subgroup of women for whom cord blood was collected (all p values <0·05).

Women in the intervention group had a significantly lower weekly rate of GWG than women in the usual care group (mean 0·26 kg per week [SD 0·15] *vs* 0·32 kg per week [0·13]; mean between-group difference –0·07 kg per week [95% CI –0·09 to –0·04]; p<0·0001; table 2). The proportion of women exceeding the Institute of Medicine guidelines for weekly rate of GWG was significantly lower in the intervention group (96 [48%] of 199) than in the usual care group (134 [69%] of 195; RR 0·70 [95% CI 0·59 to 0·83]; p<0·0001).

The intervention increased the proportion of women meeting the Institute of Medicine guidelines for weekly rate of GWG (65 [33%] *vs* 46 [24%]; RR 1·38 [95% CI 1·00–1·90]; p=0·049), as well as the proportion of women whose weekly rate of GWG was below the guidelines (38 [19%] *vs* 15 [8%]; 2·49 [1·44–4·31]; p<0·0001).

The intervention significantly reduced the proportion of women who exceeded the Institute of Medicine guidelines for total GWG (80 [41%] *vs* 128 [66%]; 0·62 [0·51 to 0·76]; p<0·0001) and increased the proportion of women meeting guidelines for appropriate total GWG (69 [36%] *vs* 42 [22%]; 1·66 [1·21–2·30]; p=0·0022); it also increased the proportion of women whose total GWG was below the Institute of Medicine guidelines (45 [23%] *vs* 24 [12%]; 1·84 [1·17–2·87]; p=0·0078; table 2). Women in the intervention group had significantly lower total GWG, gaining on average 10·21 kg (SD 5·63) compared with women in the usual care group who gained on average 12·36 kg (5·28; mean between-group difference –2·19 kg [–3·26 to –1·12]; p<0·0001). Women in the intervention group also had a significantly lower rate of GWG per week between study clinic visits at 8–15 and 29–38 weeks of gestation than women in the usual care (–0·11 kg per week [–0·15 to –0·08]; p<0·0001), and a significantly higher proportion of women in the intervention met the trial goals for total GWG (47 [24%] *vs* 24 [12%]; 1·94 [1·25–3·02]; p=0·0033; table 2). There was a suggestion that the intervention was slightly more effective among women with obesity, among whom the group differences in GWG were slightly larger than in women with overweight (table 2).

Between study clinic visits (at 8–15 and 29–38 weeks' gestation), women in the intervention group had a significantly smaller increase in caloric intake and percent of calories from saturated fat than women in usual care (table 3). No between-group differences were observed in the proportion of calories from total fat or unsaturated fat. Between study clinic visits, women in both study groups had similar changes in total moderate-intensity and vigorous-intensity physical activity, as assessed by accelerometer or self-report. However, compared with women in usual care, women in the intervention significantly reduced their self-reported sedentary behaviour (table 3).

Between study clinic visits, women in the intervention group had a significantly smaller increase in serum concentrations of fasting insulin and leptin, and smaller increases in homoeostatic model assessment of insulin resistance, than did women in the usual care group (table 3). Rate of GWG per week between study clinic visits significantly mediated the intervention's effects on changes in insulin by 67·9% (p=0·0099), homoeostatic model assessment of insulin resistance by 70·2% (p=0·016) and leptin by 90·2% (p=0·00014; appendix p 3). Cord serum concentrations of C-peptide were significantly lower in the intervention group than in the usual care group (table 4). Serum concentrations of leptin were also lower in the intervention group than in the usual care group, although not significant (table 4). No between-group differences were observed in other measured metabolic biomarkers (tables 3, 4).

Macrosomia, low birthweight, small and large for gestational age status, preterm delivery, caesarean delivery, gestational hypertension, pre-eclampsia, and gestational diabetes did not significantly differ between the intervention and the usual care group (table 5).

On average, women in the intervention group attended 11·4 (SD 3·8) core sessions. Specifically, four (2%) of 199 did not complete any session, 20 (10%) completed 1–3 sessions, eight (4%) completed 4–8 sessions, eight (4%) completed 9–12 sessions and 161 (81%) completed all 13 core sessions. On average, the first in-person session lasted 52·9 min (10·4), and the last in-person session lasted 36·8 min (11·7). Each core telephone session lasted on average 25·6 min (8·6). 151 (76%) of 199 women completed at least one maintenance telephone session. Each maintenance telephone session lasted on average 20·5 min (8·3).

Direct costs per person of the core intervention were US$277·00 ($200·30 for the dietitians's time spent for in-person and telephone sessions, according to the 2018 median annual wage for registered dietitians in the USA;[22] [$29·02 per h], plus $22·50 for printing the workbook, $35·00 for the scale, and $19·20 for the telephone charges [$0·06 per min]), whereas direct cost per person of the maintenance phase of the intervention was $36·89 ($33·48 for the dietitian's time spent for booster telephone sessions plus $3·41 for the telephone charges).

	Intervention	Usual care	Between-group difference in means* (95% CI)	p value
(Continued from previous page)				
Fasting VLDL, mmol/L‖				
8 to 15 weeks' gestation	0·6 (0·2)	0·6 (0·2)	..	..
29 to 38 weeks' gestation	1·0 (0·3)	1·0 (0·3)	..	..
Change	0·4 (0·2)	0·4 (0·3)	–0·02 (–0·07 to 0·04)	0·51
Fasting triglycerides, mmol/L§				
8 to 15 weeks' gestation	1·3 (0·4)	1·3 (0·5)	..	..
29 to 38 weeks' gestation	2·2 (0·7)	2·3 (0·8)	..	..
Change	0·9 (0·5)	1·0 (0·6)	–0·04 (–0·16 to 0·08)	0·51
Fasting free-fatty acid, mmol/L§				
8 to 15 weeks' gestation	0·5 (0·2)	0·5 (0·2)	..	..
29–38 weeks' gestation	0·5 (0·1)	0·5 (0·2)	..	..
Change	0·01 (0·2)	0·03 (0·2)	–0·02 (–0·05 to 0·02)	0·37

Data are mean (SD), unless otherwise stated. MET=metabolic equivalent. HOMA-IR=homoeostatic model assessment of insulin resistance. *Adjusted for age, race and ethnicity, pre-pregnancy BMI, medical centre, baseline diet, baseline physical activity, or baseline biomarker levels for each respective analysis. †Additional adjustment for the difference in device wear time. ‡Did not approximate normal distribution; log transformation yielded similar results as those presented. Valid data for the 24-h diet recall were available for 166 women in the intervention group and 174 in the usual care group. Valid data for physical activity assessed by accelerometer were available for 171 women in the intervention group and 183 in the usual care group. Valid data for self-reported physical activity were available for 171 women in the intervention group and 183 women in the usual care group. Blood samples were obtained at both study clinic visits for 173 women in the intervention group and 180 in the usual care group. §Assessed among 159 women in the intervention group and 171 in the usual care group who fasted at both visits. ¶Assessed among 165 women in the intervention group and 173 in the usual care group with triglycerides of 39·9 mg/L or less at both visits. ||Assessed among 163 women in the intervention group and 169 in the usual care group who fasted and had triglycerides of 39·9 mg/L or less at both visits.

Table 3: **Mean changes for diet, physical activity, and metabolic biomarkers**

Discussion

In this two-arm, parallel group randomised controlled trial, we showed that a lifestyle intervention adapted from the DPP[10] and delivered primarily by telehealth was feasible in health-care delivery settings and significantly reduced the proportion of women exceeding the Institute of Medicine guidelines for weekly rate of GWG. The intervention's effect on reduced GWG might be explained by the observed reductions in total caloric intake, proportion of calories from saturated fat, and sedentary behaviour among women in the intervention group. Significantly lower weekly rate of GWG among women in the intervention group than in the usual care group explained a large number (68–90%) of the significantly lower pregnancy-induced increases in serum concentrations of fasting insulin, homoeostatic model assessment of insulin resistance, and leptin observed in that group, which might have in turn led to lower cord blood concentrations of C-peptide and leptin.

Of the previous trials done among women with overweight or obesity with the primary goal of reducing GWG, only intensive in-person behavioural lifestyle interventions[6,7] have been successful in preventing excess GWG. A meta-analysis of such interventions in the LIFE-Moms consortium[7] showed a 17·6% reduction in the proportion of women exceeding the IOM guidelines for

	Intervention n=89		Usual care n=93		Ratio of means (95% CI)*	p value
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)		
Adiponectin, ng/mL	31·7 (15·1)	29·0 (21·9–37·0)	29·2 (10·3)	31·0 (22·6-35·7)	1·06 (0·92–1·22)	0·39
Leptin, nmol/L	1·8 (1·9)	1·1 (0·7–2·2)	2·0 (1·6)	1·5 (1·0–2·5)	0·80 (0·63–1·01)	0·063
C-peptide, nmol/L	0·2 (0·3)	0·2 (0·1–0·3)	0·3 (0·3)	0·2 (0·1–0·3)	0·72 (0·54–0·96)	0·028
Glucose, mmol/L	4·1 (1·5)	4·1 (3·3–5·0)	4·0 (1·6)	3·9 (3·2–4·8)	1·03 (0·86–1·22)	0·77
Insulin, pmol/L	40·9 (67·3)	26·4 (13·2–42·6)	39·4 (46·9)	25·5 (15·0–49·2)	0·88 (0·67–1·16)	0·37
HOMA-IR	1·5 (3·5)	0·8 (0·3-1·2)	1·4 (2·1)	0·8 (0·4-1·8)	0·88 (0·61–1·26)	0·49
Free fatty acid, mmol/L	0·2 (0·2)	0·2 (0·2-0·3)	0·2 (0·2)	0·2 (0·2–0·3)	0·97 (0·84–1·12)	0·69

HOMA-IR=homoeostatic model assessment of insulin resistance. *Adjusted for age, race and ethnicity, pre-pregnancy BMI, and medical centre. Ratio of geometric means between intervention *vs* usual care.

Table 4: **Cord serum metabolic biomarkers by study group**

	Intervention (n=195)	Usual care (n=194)	Relative risk (95% CI)*	p value
Gestational diabetes†	16 (8%)	16 (8%)	1·01 (0·53–1·94)	0·97
Gestational hypertension†	15 (8%)	15 (8%)	1·00 (0·51–1·98)	0·99
Pre-eclampsia†	9 (5%)	15 (8%)	0·58 (0·26–1·31)	0·19
Primary caesarean section†	27 (14%)	29 (15%)	0·91 (0·56–1·47)	0·70
Preterm delivery at 25–37 weeks‡	12 (6%)	12 (6%)	1·00 (0·44–2·25)	1·00
Birthweight for gestational age§				
LGA, ≥90th percentile	23 (12%)	28 (15%)	0·84 (0·50–1·41)	0·51
LGA, ≥95th percentile	15 (8%)	16 (8%)	0·93 (0·46–1·87)	0·83
SGA, ≤10th percentile	25 (13%)	18 (9%)	1·41 (0·81–2·43)	0·22
SGA, ≤5th percentile	14 (7%)	9 (5%)	1·53 (0·69–3·38)	0·29
Birthweight >4000 g§	23 (12%)	22 (11%)	1·06 (0·61–1·84)	0·83
Birthweight <2500 g§	9 (5%)	4 (2%)	2·20 (0·64–7·57)	0·21

Data are n (%), unless otherwise specified. Gestational diabetes was defined according to criteria used in the Kaiser Permanente Northern California clinical setting as two or more abnormal values during a 100 g, 3-h oral glucose tolerance test according to the Carpenter and Coustan criteria or fasting glucose value ≥5·3 mmol/L after a glucose value 1 h after a 50 g oral glucose challenge test 10·0 mmol/L or more. LGA=large for gestational age. SGA=small for gestational age. *Adjusted for age, race and ethnicity, pre-pregnancy BMI, and medical facility. †Calculated among 195 women in the intervention group and 194 women in the usual care group who did not have a pregnancy loss. ‡Calculated among 194 women in the intervention group who did not have a pregnancy loss or unknown gestational age at delivery and 194 women in the usual care group who did not have a pregnancy loss. §Calculated among 194 women in the intervention group who did not have a pregnancy loss and 190 women in the usual care group who did not have a pregnancy loss and infant birthweight was available.

Table 5: **Perinatal complications by study group**

weekly rate of GWG (61·8% in the intervention group *vs* 75·0% in the usual care group), whereas our lower intensity GLOW intervention showed a 30% reduction (48% in the intervention *vs* 69% in usual care). The between-group difference in total GWG observed in our trial was approximately 38% higher than that observed in the LIFE-Moms consortium (2·2 kg *vs* 1·6 kg). The between-group difference in total GWG among women with obesity in GLOW was similar to that observed in a high-intensity, in-person, group-based lifestyle intervention among women with obesity done by Vesco and colleagues[6] (3·5 kg *vs* 3·4 kg). Lifestyle interventions designed to improve glucose homoeostasis or reduce the risk of gestational diabetes among women at high risk and with a BMI of 29 kg/m² or higher either had no effect on GWG[23] or reduced GWG with between-group differences ranging from –2·02 kg[24] to –0·55 kg.[25]

Intensive in-person interventions might not be feasible for many women, whereas our GLOW intervention was primarily delivered by telehealth, which might have been more convenient for women, increasing adherence and thus effectiveness. Indeed, in our study, women in the intervention group had smaller increases in total caloric intake and saturated fat and decreased sedentary behaviour compared with women in the usual care group. The GLOW intervention significantly reduced the adverse pregnancy-induced changes in insulin, homoeostatic model assessment of insulin resistance, and leptin between 8–15 and 29–38 weeks' gestation; the intervention's effect on these metabolic markers was largely mediated by the reduced rate of GWG per week during the same time period in pregnancy. These positive effects on metabolic markers have not been found in the previous interventions for GWG among women with overweight or obesity[6,7,26] or at risk for gestational diabetes.[25]

In GLOW, no between-group differences were found on perinatal complications or infant birthweight. These findings are consistent with the results from the LIFE-Moms consortium[7] and from interventions done among women at risk for gestational diabetes.[23–25] A lifestyle intervention done in South Australia[27] among more than 2000 women with overweight or obesity was successful in reducing the rates of macrosomia, but not infants who were large for gestational age, although it did not have an effect of GWG. In a trial done by Vesco and colleagues[6] among 154 women with obesity, women in the lifestyle intervention group had a significantly lower proportion of infants who were large for gestational age than women in the control group.[6] Finally, a meta-analysis including individual data of more than 12 000 women from 36 randomised trials,[28] concluded that pregnancy lifestyle interventions did not reduce perinatal complications, including large for gestational age infants, although GWG was only 0·70 kg lower in the intervention than control group. However, the meta-analysis was limited by the absence of standardisation of

the intensity of the interventions and definitions of outcomes.[29]

Observational studies have reported an association between first trimester excess GWG and large for gestational age infants; therefore, perhaps interventions should start earlier in pregnancy or even before conception to affect birthweight.[30] Another possible strategy would be continuing the telehealth intervention into the post-partum period to prevent infants being large for gestational age in a subsequent pregnancy. It is possible that the GLOW intervention might reduce the risk of child adiposity in later childhood because its positive effect on GWG, diet, physical activity, insulin resistance, and leptin could reduce the risk of obesity in the offspring potentially through epigenetic pathways.[31] However, it is also possible that positive effects on the woman's lifestyle might no longer be evident once interventions are discontinued, potentially affecting the child's lifestyle and adiposity.

Finally, it should be noted that in our study's intervention group, as well as in previous intervention groups,[6,7] there was an increase in the number of women with GWG below the Institute of Medicine guidelines. This increase raises concerns because observational studies have reported that both excess and suboptimal GWG among women with normal weight, but not among women with overweight or obesity, were associated with childhood obesity.[5] Therefore, there is the need for longer follow-up of women and their children to elucidate the effect of GWG interventions on childhood obesity.

Strengths of the GLOW trial include the large sample size, the ability to recruit a racially and ethnically diverse population, including Asian women (a group underrepresented in previous trials), and the identification and enrolment of potential participants very early in gestation. The intervention's use of telehealth, which has been shown to be successful in a health-care delivery setting to improve perinatal outcomes[9] among women with gestational diabetes, is also a strength. This modality can be easily translatable to other clinical settings, one of the reasons being that cost per intervention participant was modest. Additional strengths include the use of measured weights from electronic health records.[6,7] The validity of weights from these records is supported by the similarity of the between-group difference of –0·07 kg per week in weekly rate of GWG (calculated using measured pre-pregnancy weights) and last pregnancy weight from the records with the between-group difference of –0·11 kg per week in rate of GWG per week between the two study clinic visits (calculated using weights measured according to a rigorous study protocol).

There were also some limitations to our study. Participants were not masked to study group, which could have biased responses to self-reported measures of diet and physical activity. Additionally, women in the usual care group did not receive any extra contacts with research study intervention staff, while women in the intervention group did; therefore, it is not possible to assess whether the observed between-group differences in GWG were attributable to increased contact time or to the intervention content itself. However, the latter is plausible given that even lifestyle intervention trials with active comparison groups have yielded improved GWG.[7]

In conclusion, the GLOW intervention, delivered primarily by telehealth and designed to be feasible in health-care delivery settings, was effective in substantially decreasing excess GWG, improving pregnancy diet, sedentary behaviour, markers of insulin resistance, leptin concentrations, and cord blood concentrations of C-peptide and leptin. This intervention could be an evidence-based programme that health-care delivery systems can further adapt to the needs of their clinical settings to prevent excess GWG and improve health behaviours and markers of insulin resistance among women with overweight or obesity. No between-group differences in perinatal complications were observed; however, the GLOW trial was not powered to assess differences in these outcomes. Notably, although larger trials with longer follow-up periods are needed to assess the effect of reduced GWG on perinatal and long-term outcomes, obesity prevention efforts in women of reproductive age are urgently needed to reduce complications associated with obesity.

Contributors

AF had full access to all the data in the trial and takes responsibility for the integrity of the data and the accuracy of the data analysis. AF, MMH, SDB, and CPQ contributed to the study concept and design. AF, CPQ, MMH, SDB, SFE, and MG contributed to data acquisition. AF, CPQ, MMH, SDB, SFE, A-LT, and JF contributed to analysis and interpretation of data. AF drafted the manuscript. AF, CPQ, MMH, SDB, SFE, PC, and SM contributed to the critical revision of the manuscript for important intellectual content.

Declaration of interests

We declare no competing interests.

Data sharing

A de-identified analytic dataset with an accompanying data dictionary used in this study can be shared with qualified researchers who request the data to replicate the results shown in this Article subject to approval by the Kaiser Foundation Research Institute Human Subjects Committee and by the Human Subjects Committee at the institutions requesting the data and a signed data sharing agreement. Please send all requests to the corresponding author of this Article. Data will be available to requesters from 1 year after the date of publication of this Article. The study protocol and the statistical analysis plan are available in the appendix.

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