OBSTETRICS

Effect of antenatal dietary interventions in maternal obesity on pregnancy weight-gain and birthweight: Healthy Mums and Babies (HUMBA) randomized trial

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BACKGROUND: Pregnancy interventions that improve maternal and infant outcomes are urgently needed in populations with high rates of obesity. We undertook the Healthy Mums and Babies (HUMBA) randomized controlled trial to assess the effect of dietary interventions and or probiotics in a multiethnic population of pregnant women with obesity, living in an area of high deprivation.

OBJECTIVES: To determine whether a culturally tailored dietary intervention and or daily probiotic capsules in pregnant women with obesity reduces the co-primary outcomes of (1) excessive gestational weight gain (mean >0.27 kg/week) and (2) birthweight.

STUDY DESIGN: We conducted a 2 × 2 factorial, randomized controlled trial in women without diabetes at pregnancy booking, body mass index ≥30 kg/m^2, and a singleton pregnancy. At 12^{+0} to 17^{+6} weeks' gestation, eligible women were randomized to a dietary intervention (4 tailored educational sessions at ≤28 weeks' gestation by a community health worker trained in key aspects of pregnancy nutrition plus text messaging until birth) or to routine dietary advice; and to daily capsules containing either (*Lactobacillus rhamnosus* GG and *Bifidobacterium lactis* BB12, minimum 6.5 × 10^9 colony forming units), or placebo, until birth. Analysis was by intention to treat with adjustment for maternal baseline body mass index. Infant outcomes were additionally adjusted for ethnicity, sex, and gestational age at birth.

RESULTS: In total, 230 women were recruited between April 2015 and June 2017 (dietary intervention N = 116 vs routine dietary advice N = 114; probiotics N = 115 vs placebo N = 115). Baseline characteristics and demographic variables were similar across all groups. There was no significant difference between intervention groups, for the co-primary outcomes of (1) proportion of women with excessive gestational weight gain (dietary intervention vs routine advice: 79/107 [73.8%] vs 90/110 [81.8%], adjusted relative risk [relative risk, 0.92; 95% confidence interval, 0.80—1.05]; probiotics versus placebo: 89/108 [82.4%] and 80/109 [73.4%], relative risk, 1.14, 95% confidence interval, 0.99—1.31) or (2) birthweight (dietary intervention vs routine advice: 3575 vs 3612 g, adjusted mean difference, —24 g, 95% confidence interval, —146 to 97; probiotics vs placebo: 3685 vs 3504 g, adjusted mean difference, 107 g, 95% confidence interval, —14 to 228). Total maternal weight gain, a secondary outcome, was lower with dietary intervention compared with routine dietary advice (9.7 vs 11.4 kg, adjusted mean difference, —1.76, 95% confidence interval, —3.55 to 0.03). There were no significant differences between intervention groups in other secondary maternal or neonatal outcomes.

CONCLUSION: Although dietary education and or probiotics did not alter rates of excessive gestational weight gain or birthweight in this multiethnic, high-deprivation population of pregnant women with obesity, dietary education was associated with a modest reduction in total weight gain with potential future benefit for the health of mothers and their offspring if sustained.

Key words: community health worker, gestational weight gain, probiotics, text messaging

Obesity during pregnancy is a concern for obstetricians globally, particularly in populations with high rates of obesity.[1] The United States is rated first and New Zealand as third-most obese among the Organization for Economic Co-operation and Development countries.[2] In New Zealand, the greatest rates of obesity are among Pacific (69%) and Māori (50%). Of concern, 12% of children in New Zealand are obese, and obesity rates are greater in those living in areas of high deprivation.[3] The Counties Manukau Health region in South Auckland is home to an ethnically diverse population with high rates of obesity, where approximately 70% of women giving birth reside in areas of high deprivation.[4] Poor living conditions, overcrowding, and poor nutrition further contribute to adverse health outcomes of women living in the region.[4-6] Native Hawaiians and Pacific Islanders in the United States have similar characteristics to the South Auckland population, with high rates of obesity and similar health outcomes.[7]

Obesity during pregnancy is a risk factor for many maternal and infant complications, including gestational diabetes mellitus (GDM) and pre-eclampsia, and increased fetal exposure to excessive nutrients, resulting in large-for-gestational age (LGA) infants.[8-11] A recent review highlighted maternal obesity as a major determinant of health during childhood and later adult life, increasing risks of noncommunicable diseases[12] and potentially contributing to the enormous obesity-related health costs.[13] Excessive gestational weight gain (GWG) is more common in women with

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AJOG at a Glance

Why was the study conducted?

To test whether dietary education and or probiotic capsules (*Lactobacillus rhamnosus* GG and *Bifidobacterium lactis* BB-12) could reduce excessive gestational weight gain and birthweight in a multiethnic New Zealand population with obesity.

Key findings

Dietary education and or probiotics did not reduce the proportion of women with excessive gestational weight gain or birthweight, but dietary intervention resulted in a 1.8-kg reduction in total pregnancy weight gain.

What does this add to what is known?

Our findings are consistent with meta-analyses that showed 0.7 to 1.4kg reduction in total pregnancy weight gain with dietary interventions, confirming that dietary education effects are generalizable to high-deprivation, multiethnic populations with obesity. Our findings add to the limited literature on probiotic treatment and pregnancy outcome. We also confirmed the feasibility of undertaking a randomized trial of dietary intervention in this setting.

obesity and has similar consequences for mothers and their offspring as maternal obesity.[14-16]

Dietary and physical activity interventions during pregnancy can reduce maternal GWG and improve maternal and infant outcomes and are therefore of relevance to obstetricians.[17-19] Long-term health benefits for mothers and children also are reported.[20] However, few interventions have been undertaken in low socioeconomic settings, in which more challenges are encountered.[21] Despite challenges, dietary interventions delivered by community health workers offer a potential solution and are more affordable in a constrained healthcare environment than dietary interventions provided by dietitians. Community health workers, providing a culturally designed diabetes intervention in nonpregnant populations in American Samoa, resulted in improved diabetes control. In addition, modern delivery of text messaging can penetrate most communities[22,23] and has assisted in reducing weight in nonpregnant populations.[24]

Other potential interventions include use of probiotics (naturally occurring micro-organisms that, when ingested in adequate amounts, may confer health benefits to the host).[25] The potential positive effect of probiotics on metabolic health including glucose homeostasis[26] in products containing predominantly *Lactobacillus* and *Bifidobacteria* was reported in a recent meta-analysis in pregnant women from European countries.[27] In addition, *Lactobacillus rhamnosus* in milk products has been associated with reduced severe preeclampsia in an observational study (adjusted odds ratio, 0.79; 95% confidence interval [CI], 0.66−0.96)[28] and in capsule form reduced postnatal depression (effect size, −1.2; 95% CI, −2.3 to −0.1) Edinburgh Postnatal Depression Score and reduced anxiety (effect size, −1.0; 95% CI, −1.9, to −0.2).[29] The most compelling metabolic benefits in pregnancy were reported in a Finnish study of 256 women randomized to dietary counselling supplemented with probiotics (*Lactobacillus rhamnosus* GG and *Bifidobacterium lactis* BB12) or placebo. There was a 64% reduction in GDM in the probiotic compared with placebo group but no difference in GWG or birthweight.[30] In contrast, a recent randomized trial in 411 overweight and obese predominantly European pregnant women did not find that probiotic capsules reduced GDM (18.4% probiotic arm vs 12.3% placebo, $P = .10$), but probiotic treatment was associated with reduced excessive GWG (32% probiotic vs 46% placebo, $P = .01$).[31]

As few previous intervention studies have been conducted in multiethnic populations with obesity,[32] the Healthy Mums and Babies (HUMBA) trial was designed to determine whether a tailored dietary intervention (dietary education [including goals] provided by community health workers and complemented by text messaging),[23] and or probiotic capsules, could reduce excessive GWG and birthweight in pregnant women with obesity in South Auckland, NZ. We hypothesized that the HUMBA trial interventions would reduce excessive GWG and birthweight.[33]

Materials and Methods

Trial design and setting

This was a single-center, 2 × 2 factorial randomized controlled demonstration trial[34] in the Counties Manukau Health Region of South Auckland, NZ. Ethics approval was obtained from the Southern Health and Disability ethics committee, NZ (14/STH/205). The HUMBA Trial was registered with the Australian NZ Clinical Trials Registry (ACTRN12615000400561). As the trial protocol has been published,[33] only brief details are provided here.

Participants

Women with a singleton pregnancy at 12^{+0} to 17^{+6} weeks of gestation and body mass index (BMI) ≥30 kg/m^2 who provided informed written consent were eligible. Exclusion criteria were preexisting diabetes or hemoglobin A1c ≥50 mmol/mol,[35] known congenital abnormality, taking capsules or supplements containing probiotics, previous bariatric surgery, severe hyperemesis, and medications or medical conditions that alter glucose metabolism.

Randomization and concealment of allocation

Eligible women were allocated randomly by the research midwife using a web-based randomization program (http://randomize.net) using random permuted blocks of 4−8 participants, stratified by BMI (30 to <35 or ≥35 kg/m^2), to dietary intervention and probiotic or placebo capsules or routine dietary advice and probiotic or placebo

capsules. Christian Hansen (Chr. Hansen A/S, Horsholm, Denmark) provided identically packaged canisters containing either probiotic or placebo capsules. AnQual Laboratories (School of Pharmacy, University of Auckland) labeled the canisters using a preallocated random list that was password protected.[33] Participants, researchers, and data analysts were blinded to probiotic and placebo allocation. Participants in the dietary intervention could not be blinded but researchers collecting and analyzing outcome data were unaware of the dietary treatment allocation.

Interventions

Women allocated to the dietary intervention received a HUMBA handbook with information about healthy nutritious foods, recipes, unhealthy drinks, managing cravings, and ways to be more physically active. In addition, they received 4 home-based education sessions by a community health worker with an Auckland University of Technology Certificate of Pacific Nutrition[36] and trained in Healthy Conversations.[37,38] This included behavior change techniques to promote healthy eating and setting SMARTER goals (specific, measurable, action-oriented, realistic, timed, evaluated, and reviewed).[39] During subsequent intervention visits, community health workers plotted the woman's weight on a personal pregnancy weight-gain chart[33] and provided feedback and positive reinforcement for goals achieved. A dietitian developed an operation manual and provided oversight. Dietary intervention visits were aimed to be completed before the 26−28 weeks' HUMBA study 75-g oral glucose tolerance test (OGTT).

Women in the dietary intervention also received motivational text messages 3 times weekly from randomization until birth. Content of the messages was designed to complement dietary education with some worded as if from the baby to the mother, eg, "Mum, remember to read food labels." Women could elect to stop receiving texts at any time.

Women allocated to routine dietary advice received the NZ Ministry of Health pamphlets "Eating for healthy pregnant women"[40] and "Healthy weight-gain in pregnancy,"[41,42] with no dietary input from community health workers or text messages.

Women allocated to probiotics received capsules containing *Lactobacillus rhamnosus* GG and *Bifidobacterium lactis* BB12 (minimum dose 6.5×10^9 colony forming units; www.chr-hansen.com). Women in the placebo group received identical capsules containing microcrystalline cellulose and dextrose anhydrate. Women were instructed to take 1 capsule (probiotic or placebo) daily until birth. All participants continued routine antenatal care.

Assessments

At recruitment (12^0-17^6 weeks), a research midwife took detailed demographic, medical, and obstetric history. Physical measurements included blood pressure, height, weight, waist, and arm circumference obtained using standard techniques.[33] Hemoglobin A1c and lipid concentrations were measured with the cobas b 101 point-of-care system (Roche Diagnostics International Ltd, Risch-Rotkreuz, Switzerland). The women completed standardized questionnaires including the NZ Food Frequency-Short Form,[43] NZ Physical Activity-Short Form,[44] and 3 psychological questionnaires (State Trait Anxiety Index Short-Form,[45] Short Form Health Survey,[46] and Edinburgh Postnatal Depression Scale[47]).

At 26−28 weeks' gestation, participants underwent a 75-g OGTT with measurement of fasting, 1- and 2-hour glucose concentrations, and were referred to the diabetes in pregnancy service if they met the NZ Study of Diabetes diagnostic criteria (fasting $\geq$5.5 and 2 hour $\geq$9.0 mmol/L).[35]

At 28 weeks' gestation, obstetric history and anthropometric measurements were obtained by the research midwife, and women completed the NZ Food Frequency-Short Form[43] and NZ Physical Activity-Short Form questionnaires.[44] At 36 weeks' obstetric history and anthropometric measurements were obtained and women repeated the 3 psychological questionnaires.[45-47]

Compliance with capsules was defined as taking probiotic or placebo capsules >75% of the time and was assessed by participant verbal feedback at 28 weeks, 36 weeks and post-birth. Compliance with the dietary intervention was defined as completing 3 or 4 dietary intervention visits with the community health worker.

Within 72 hours of birth, a member of the research team collected outcome data including last recorded weight before birth; pre-labor blood pressure and proteinuria; any illnesses, hospital admissions or antibiotic use since the last HUMBA visit; feedback about HUMBA capsules and compliance; and all labor and birth outcomes. Neonatal length, head, chest, waist, and left mid-arm circumferences and skin-fold thicknesses (subscapular, triceps, and suprailiac to the nearest 0.2 mm) were recorded.[33] Whole-body fat and lean mass were measured by air-displacement plethysmography according to the manufacturer's instructions (Pea Pod; COSMED USA, Concord, CA) using reference data of Fomon et al.[48]

Outcomes

The primary maternal outcome was the proportion of women with excessive GWG defined as mean weekly weight gain >0.27 kg between recruitment and 36 weeks' gestation (or closest weight), adjusted for baseline BMI.[49-51] The primary infant outcome was birthweight adjusted for gestation, infant sex, maternal baseline BMI, and self-reported ethnicity. This outcome was chosen as shifts in birthweight have potential to influence long-term health, including obesity.[52]

Secondary maternal outcomes included total maternal GWG adjusted for gestation (last pregnancy weight minus weight at recruitment), OGTT, and hemoglobin A1c results at 28 and 36 weeks, GDM by International and New Zealand Study of Diabetes criteria, pregnancy-induced hypertension,[53] depression,[54] anxiety,[45] and mode of birth.

Infant secondary outcomes included neonatal anthropometry, body composition, gestation at birth, rate of LGA

(birthweight >90th centile) and small for gestational age (birthweight <10th centile), admission to neonatal intensive care unit (NICU), and composite neonatal morbidity (refer to HUMBA Protocol).[33]

Sample size and statistical analysis

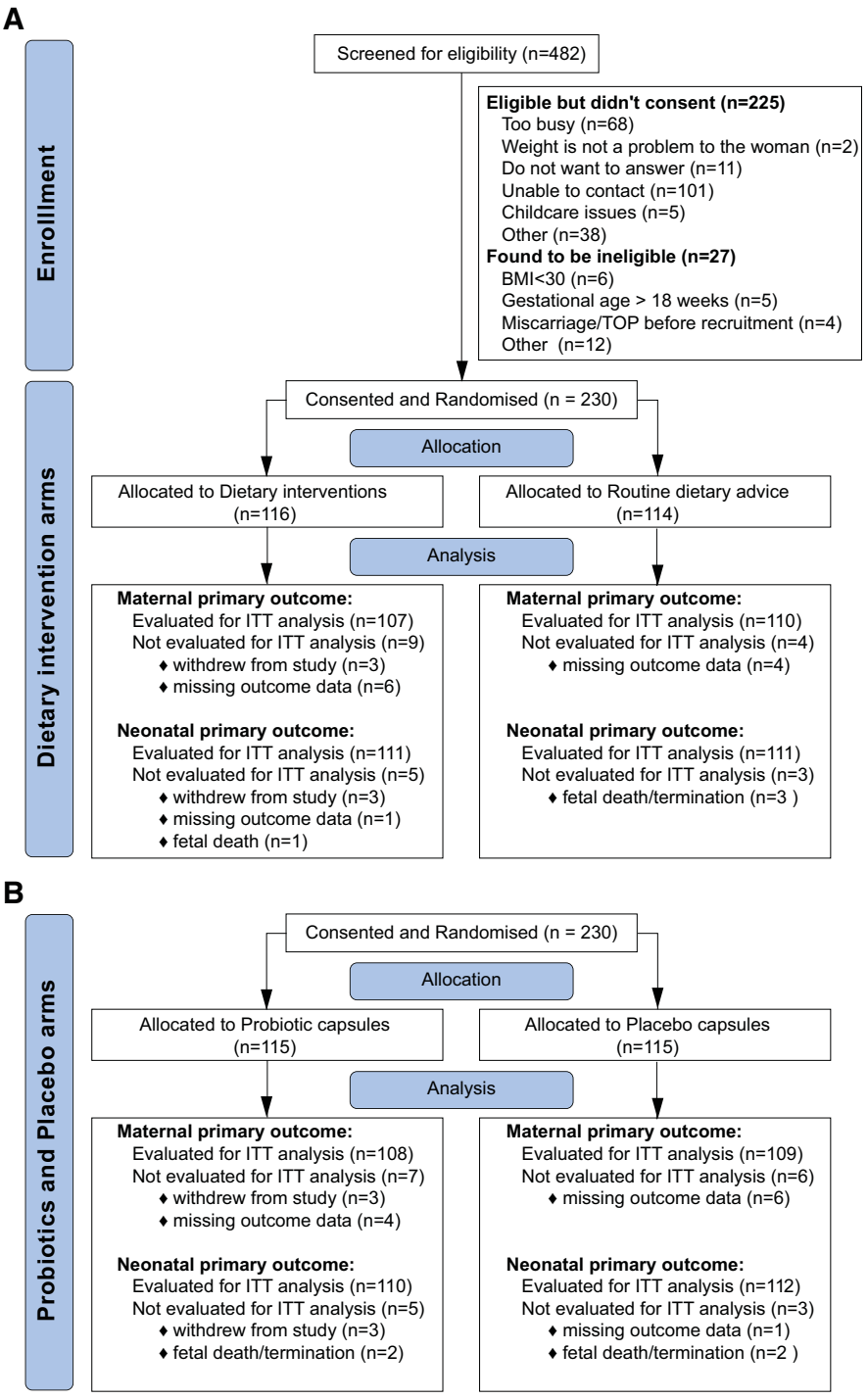
We estimated that a total sample size of 220 women would provide at least 80% power to detect a 25% reduction in excessive GWG from 80%[55] to 60% with either intervention, and 100 infants in each main intervention group (allowing for 10% loss to follow-up) could detect a 227-g difference in birth weight, assuming a mean (standard deviation [SD]) birthweight of 3638 (521) g.[56] A 2-sided alpha level of <0.025 was specified for the co-primary outcomes (Bonferroni adjustment) and <0.05 for the secondary outcomes.

Analyses were performed with SAS 9.4 (SAS Institute Inc, Cary, NC) by intention-to-treat. Binary endpoints were analyzed using modified Poisson regression models[57] to estimate relative risks for each of the interventions (dietary intervention and probiotics). Continuous outcomes were calculated using generalized linear models to estimate any changes in outcomes with the interventions (dietary intervention and probiotics) compared with their respective control groups. Primary analyses reported marginal effects for each randomized exposure, with adjustment for cointervention and prespecified covariates, as defined previously. Interactions between the main effects were tested for primary outcomes, although the trial was only powered for the main effects. Sensitivity analysis for the primary outcomes was performed in women who were compliant with the trial interventions.

Results

Between April 2015 and June 2017, 482 women were referred of whom 230 were enrolled (Figure 1). Key demographic characteristics were similar between those who did and did not agree to participate (Table 1). Among participants, the mean age (SD) was 28.8 (5.7) years and mean BMI (SD) was 38.8 (6.1) kg/m^2. More than 60% resided in areas with the highest national deprivation quintile (20% expected) and one third were not born in New Zealand. The ethnic distribution of participants was similar to the local birthing population.[4] Baseline characteristics were balanced between groups, for both randomization

FIGURE 1
Consort flow chart for the HUMBA trial



BMI, body mass index; *HUMBRA*, Healthy Mums and Babies; *ITT*, intention to treat; *TOP*, termination of pregnancy.

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TABLE 1
Comparison between women who consented or declined to participate

Variables	Consented N = 230	Declined N = 225	P value
Maternal age, y	28.8 (5.7)	27.9 (5.7)	.10
Weight, kg	107.1 (17.9)	105.9 (18.5)	.51
Height, cm	166.2 (6.2)	166.6 (5.6)	.42
BMI, kg/m^2	38.8 (6.1)	38.0 (5.7)	.22
Ethnicity[a]			.60
New Zealand Māori	52 (22.6)	33 (14.7)	
Cook Island Māori	28 (12.2)	18 (8.0)	
Samoan	46 (20.0)	74 (32.9)	
Tongan	27 (11.7)	53 (23.6)	
Other Pacific Island	13 (5.7)	4 (1.8)	
European	42 (18.3)	27 (12.0)	
Indian	13 (5.7)	9 (4.0)	
Other	9 (3.9)	7 (3.1)	

Data are presented as mean (standard deviation) or n (%).

BMI, body mass index.

[a] Prioritized ethnicity.

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factors (dietary intervention N = 116 vs routine dietary advice N = 114; and probiotics N = 115 vs placebo N = 115) (Table 2). Eighty-one percent of women were compliant with dietary interventions (94/116), and 76% met the criteria for compliance with probiotic capsules (87/115). No serious adverse events were attributed to trial interventions by the Data Safety Monitoring Committee.

Primary outcomes

There was no significant difference between intervention groups for the primary maternal outcome of excessive GWG, for either randomization factor (dietary intervention vs routine advice [73.8% vs 81.8%, adjusted risk ratio {RR}, 0.92; 95% CI, 0.80−1.05]; probiotic vs placebo [82.4% vs 73.4%, adjusted RR, 1.14; 95% CI, 0.99−1.31]) (Table 3). There was no significant difference between intervention groups for the primary neonatal outcome of birthweight, for either randomization factor (dietary vs routine: mean [SD] 3575 [609] g and 3612 [646] g, adjusted mean difference [MD], −24; 95% CI, −146 to 97 g; probiotic vs placebo: mean [SD] 3685 [565] g and 3504 [672] g, adjusted MD, 107; 95% CI, −14 to 228 g) (Table 4). There was no significant interaction between randomization factors for the primary maternal ($P = .89$) and neonatal ($P = .48$) outcomes.

Secondary Outcomes

Women who received the dietary intervention compared with routine dietary advice had a marginally significant reduction in total GWG (mean [SD] 9.7 [6.6] vs 11.4 [6.3] kg; adjusted MD, −1.76; 95% CI, −3.55 to 0.03, $P = .05$). There were no significant differences in any of the other secondary maternal outcomes between intervention groups for either randomization factor, including glucose metabolism, GDM, hemoglobin A1c levels at 28 and 36 weeks, State Trait Anxiety Index Short-Form and Edinburgh Postnatal Depression Scale scores at 36 weeks, pregnancy-induced hypertension, and mode of birth (Table 3).

There was no significant difference between intervention groups for any of the neonatal secondary outcomes, for both randomization factors, including gestational age at birth, anthropometric and body composition outcomes, preterm birth, admission to the NICU, and composite morbidity (Table 4).

Secondary analysis

In sensitivity analysis, exclusion of women who were noncompliant with the dietary intervention did not alter the results for the primary outcomes for this factor. However, among women who were compliant with capsules, those who received probiotics were more likely to have excessive GWG than those who received placebo (72/87 [82.8%] vs 64/91 [70.3%], adjusted RR, 1.18; 95% CI, 1.00−1.39, $P = .04$) and although not significantly different, birthweight was greater (3701 [583] vs 3540 g [657] g, adjusted MD, 108; 95% CI, −20 to 235, $P = .10$).

Discussion

Neither the tailored dietary intervention nor probiotics had a significant effect on the proportion of women with excessive GWG or birthweight in this multiethnic population of pregnant women with obesity, although the dietary intervention was associated with less total GWG than routine dietary advice. The interventions did not affect other maternal secondary outcomes including glucose metabolism, risk of developing GDM, pregnancy-induced hypertension, caesarean delivery, or psychological measures of well-being. Similarly, neither intervention altered neonatal anthropometry, body composition, or neonatal morbidity. In the secondary analysis of women compliant with capsules, probiotic treatment was associated with an increase in excessive GWG.

Our finding of a 1.76-kg reduction in total GWG following dietary intervention is similar to that in 2 recent meta-analyses in women of any BMI. One showed a 1.42-kg (95% CI, 0.95−1.89 kg; $I^2 = 80\%$) reduction in GWG[17] and the other, which analyzed individual participant data,[32] a −0.70-kg (95% CI, −0.92 to −0.48 kg, $I^2 = 14.1\%$) reduction in GWG. In a subgroup of obese and overweight women, dietary

TABLE 2
Characteristics of trial participants at recruitment

Characteristics	Dietary intervention N = 116	Routine dietary advice N = 114	Probiotic N = 115	Placebo N = 115
Age, y	29.8 (5.7)	27.8 (5.5)	28.9 (5.7)	28.6 (5.7)
Weight, kg	109.0 (18.9)	105.3 (18.3)	108.0 (20.0)	106.4 (17.3)
Height, cm	166.6 (5.8)	166.5 (6.0)	166.4 (6.1)	166.8 (5.6)
BMI, kg/m^2	39.2 (6.2)	37.9 (5.9)	38.9 (6.5)	38.2 (5.7)
BMI category, kg/m^2, n (%)				
30–34.9	35 (30.2)	38 (33.3)	36 (31.3)	37 (32.2)
>35.0	81 (69.8)	76 (66.7)	79 (68.7)	78 (67.8)
Ethnicity, n (%)				
New Zealand Māori	25 (21.6)	27 (23.7)	25 (21.7)	27 (23.5)
Cook Island Māori	16 (13.8)	12 (10.5)	15 (13.0)	13 (11.3)
Samoan	23 (19.8)	23 (20.2)	24 (20.9)	22 (19.1)
Tongan	14 (12.1)	13 (11.4)	13 (11.3)	14 (12.2)
Other Pacific Island	8 (6.9)	5 (4.4)	6 (5.2)	7 (6.1)
Caucasian	21 (18.1)	21 (18.4)	18 (15.7)	24 (20.9)
Indian	6 (5.2)	7 (6.1)	9 (7.8)	4 (3.5)
Other	3 (2.6)	6 (5.3)	5 (4.4)	4 (3.5)
Parity, n (%)				
0	30 (25.9)	43 (37.7)	35 (30.4)	38 (33.0)
1–3	70 (60.3)	62 (54.4)	69 (60.0)	63 (54.8)
≥4	16 (13.8)	9 (7.9)	11 (9.6)	14 (12.2)
Didn't complete high school, n (%)	35 (30.2)	34 (29.8)	35 (30.4)	34 (29.6)
Paid employment, n (%)	55 (47.4)	60 (52.6)	60 (52.2)	55 (47.8)
Highest deprivation quintile, n (%)	72 (62.1)	76 (66.7)	79 (68.7)	69 (60.0)
Married/civil union, n (%)	65 (56.0)	59 (51.8)	69 (60.0)	55 (47.8)
Current smoker, n (%)	17 (14.7)	15 (13.2)	15 (13.0)	17 (14.8)
Gestation at recruitment, wk, n (%)	15.3 (1.9)	14.9 (1.7)	15.2 (1.8)	15.1 (1.8)
EPDS – proportion abnormal n, (%)	11/116 (9.5)	20/113 (17.7)	14/115 (12.2)	17/114 (14.9)
STAI-SF – proportion abnormal, n (%)	3/116 (2.6)	5/113 (4.4)	2/115 (1.7)	6/114 (5.3)
Family history, n (%)				
Family history of chronic hypertension[a]	51 (44.0)	49 (43.0)	49 (42.6)	51 (44.4)
Family history of diabetes[a]	45 (38.8)	48 (42.1)	51 (44.4)	42 (36.5)
Medical history, n (%)				
Chronic hypertension	13 (11.2)	9 (7.9)	10 (8.7)	12 (10.4)
Depression	13 (11.2)	17 (14.9)	10 (8.7)	20 (17.4)
Asthma	13 (11.2)	15 (13.2)	18 (15.7)	10 (8.7)

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(continued)

intervention was associated with a 2.1-kg (95% CI, −3.46 to −0.75; I^2 = 88%) reduction in GWG.[17] Consistent with our trial, no significant effect of dietary and physical activity interventions on birthweight have been reported.[17,32] In line with our trial, the individual participant data meta-analysis reported that dietary and or

TABLE 2
Characteristics of trial participants at recruitment *(continued)*

Characteristics	Dietary intervention N = 116	Routine dietary advice N = 114	Probiotic N = 115	Placebo N = 115
Obstetric history,[b] n (%)	N = 85	N = 71	N = 80	N = 76
Cesarean delivery	23 (27.1)	21 (29.6)	25 (31.3)	19 (25.0)
Gestational diabetes mellitus	4 (4.7)	2 (2.8)	3 (3.8)	3 (3.9)
Hypertension in pregnancy[c]	16 (18.8)	18 (25.4)	16 (20.0)	18 (23.7)
Preterm birth	12 (14.1)	8 (11.3)	10 (12.5)	10 (13.2)
Stillbirth/neonatal death	6 (7.1)	5 (7.0)	7 (8.8)	4 (5.3)

Data are mean (standard deviation) or n (%).

BMI, body mass index; *EPDS*, Edinburgh Postnatal Depression Scale; *STAI-SF*, State Trait Anxiety Inventory Score-Short Form.

[a] History of mother, father, or sibling with condition; [b] Nulliparous excluded; [c] Defined as previous history of gestational hypertension or pregnancy-induced hypertension or preeclampsia.

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physical activity interventions did not alter small-for-gestational-age or LGA infants, stillbirth, NICU admission, or composite maternal and neonatal outcomes.[32] In contrast to the HUMBA Trial, both dietary and physical activity interventions reduced caesarean delivery (RR, 0.91; 95% CI, 0.83−0.99) whereas dietary interventions reduced rates of preterm birth (RR, 0.28; 95% CI, 0.08−0.96).[32] These differences may be due to the differences in participant characteristics, as the meta-analysis populations were more than 80% white, 50% of high socioeconomic status, and only 40% had obesity.

Our findings for the probiotic intervention contrast with a Finnish trial that used the same probiotics[30] and another trial using *Lactobacillus rhamnosus*[58] that reported reduced rates of GDM with probiotics. The recently reported Study of Probiotics IN prevention of Gestational diabetes study,[31] which used the same probiotics as our trial, also did not observe a reduction in GDM (18.3% probiotic and 12.3% placebo, $P = .10$). Consistent with the findings from our study, a recent meta-analysis investigating preterm birth prevention in healthy pregnant women (n = 4098) showed that probiotics did not affect birthweight, LGA, risk of GDM, or preterm birth.[59] Previous studies have reported that women receiving probiotics have less pregnancy-induced hypertension[28] and depression or anxiety[29]; however, we were unable to demonstrate this in our trial.

Our finding that excessive GWG was more common in mothers compliant with probiotics should be interpreted with caution, as our assessment of compliance (participant self-report) was suboptimal. However, these findings are consistent with those from a meta-analysis of randomized trials[60] that showed that a probiotic frequently used in humans (*Lactobacillus acidophilus*) resulted in increased weight in lean nonpregnant adults (standardized MD, 0.15; 95% CI, 0.05 to 0.25; p = .005, I^2 = 42%). In contrast, the SPRING trial of probiotics in overweight and obese predominantly European women reported that excessive GWG was less common in women who received probiotics (32.5% vs 46%, $P = .01$).[31]

The modest reduction in total GWG in pregnancy with the dietary intervention, if sustained, could have longer-term health benefits, as increases in weight as little as 1.5%−2.5% or 1 BMI unit (2.7 kg) between pregnancies have been associated with increased GDM, preeclampsia, and LGA in the next pregnancy.[61-63]

This was the first trial of a tailored dietary intervention and/or probiotics performed in a multiethnic population of predominantly Pacific and Māori pregnant women with obesity living in high deprivation. We have demonstrated the feasibility of carrying out a complex trial in a population that has significant barriers to engaging with antenatal care.[64] Importantly, women who participated were similar to those who chose not to participate, suggesting our results are broadly generalizable to the population of interest. In contrast to previous literature, which has reported low rates of participation of ethnic minorities in pregnancy research,[65] we achieved high participation among Māori and Pacific women, with >90% primary outcome data collected.

Success with providing the dietary interventions was due to the ability of community health workers to meet women at their desired location and provide a culturally tailored intervention. Having community health workers with similar ethnicity as the majority of the participants, as recommended by a previous multicenter report,[66] may have assisted with participant engagement.

Our assessment of compliance with dietary intervention as number of visits attended was pragmatic but is an insufficient measure of adherence to dietary intervention. Similarly, compliance with pills, relied largely on self-report, and is less reliable than pill counting.

Conclusion

Neither a tailored dietary intervention nor probiotics altered rates of excessive GWG or birthweight in this multiethnic,

TABLE 3
Maternal primary and secondary outcomes

Outcomes	Dietary intervention N = 116	Routine dietary advice N = 114	Adjusted treatment effect RR or MD (95% CI)	*P* value	Probiotic N = 115	Placebo N = 115	Adjusted treatment effect RR or MD (95% CI)	*P* value
Primary outcome								
Excessive weight gain (>0.27 kg/wk)[a]	79/107 (73.8)	90/110 (81.8)	0.92 (0.80–1.05)	.22	89/108 (82.4)	80/109 (73.4)	1.14 (0.99–1.31)	.08
Secondary outcomes								
Weight change baseline to 36 wk[b]	9.7 (6.6) N = 100	11.4 (6.3) N = 101	−1.76 (−3.55, 0.03)	.05	11.0 (6.5) N = 100	10.1 (6.5) N = 101	0.86 (−0.95, 2.67)	.35
GDM (IADPSG criteria)[a] n/N(%)	30/96 (31.3)	23/100 (23.0)	1.31 (0.83–2.09)	.25	28/105 (26.7)	25/91 (27.5%)	0.94 (0.59–1.49)	.80
Fasting glucose OGTT, mmol/L	4.6 (0.5) N = 96	4.6 (0.5) N = 100	0.00 (−0.14, 0.14)	.94	4.6 (0.5) N = 105	4.7 (0.5) N = 91	−0.06 (−0.20, 0.08)	.37
1-h glucose OGTT, mmol/L	8.1 (1.8) N = 67	8.1 (1.6) N = 72	0.05 (−0.52, 0.62)	.86	8.0 (1.6) N = 75	8.1 (1.8) N = 64	−0.10 (−0.67, 0.47)	.72
2-h glucose OGTT, mmol/L	6.3 (1.4) N = 96	6.2 (1.2) N = 99	0.04 (−0.33, 0.41)	.83	6.3 (1.3) N = 105	6.2 (1.3) N = 90	0.04 (−0.33, 0.41)	.84
HbA1c 36 wk[a]	38.1 (5.0) N = 81	37.0 (4.0) N = 79	0.93 (−0.48, 2.33)	.19	37.9 (4.6) N = 84	37.3 (4.5) N = 76	0.56 (−0.83, 1.96)	.43
EPDS 36 wk — proportion abnormal, n/N (%)	9/83 (10.8)	7/81 (8.6)	1.25 (0.49–3.21)	.64	8/88 (9.1)	8/76 (10.5)	0.86 (0.34–2.19)	.76
STAI-SF score 36 wk — proportion abnormal, n/N (%)	7/85 (8.2)	3/79 (3.8)	2.17 (0.58–8.10)	.25	6/87 (6.9)	4/77 (5.2)	1.33 (0.39–4.53)	.65
Pregnancy-induced hypertension[a]	8/110 (7.3)	10/111 (9.0)	0.78 (0.32–1.90)	.58	11/108 (10.2)	7/113 (6.2)	1.61 (0.64–4.09)	.31
Mode of birth, n (%)	N = 112	N = 114			N = 112	N = 114		
Unassisted vaginal birth[a]	67 (59.8)	72 (63.2)	0.91 (0.53–1.56)	.72	64 (57.1)	75 (65.8)	0.71 (0.41–1.21)	.21
Operative vaginal birth[a]	6 (5.4)	5 (4.4)	1.21 (0.36–4.15)	.76	7 (6.3)	4 (3.5)	1.82 (0.52–6.42)	.35
Total cesarean deliveries[a]	39 (34.8)	36 (31.6)	1.11 (0.63–1.95)	.71	40 (35.7)	35 (30.7)	1.23 (0.70–2.15)	.47
Emergency cesarean deliveries[a]	14 (12.5)	19 (16.7)	0.71 (0.34–1.51)	.37	21 (18.8)	12 (10.5)	1.97 (0.92–4.23)	.08
Stillbirth	1 (0.9)	3 (2.6)	0.33 (0.03–3.25)	.34	2 (1.8)	2 (1.8)	1.02 (0.14–7.36)	.99

Data are mean (standard deviation) or n (%) as marked.

Interaction test for primary maternal outcome P = .89.

BMI, body mass index; *CI*, confidence interval; *EPDS*, Edinburgh Postnatal Depression Scale; *GDM*, gestational diabetes mellitus; *HbA1c*, hemoglobin A1c; *IADPSG*, International Association of Diabetes and Pregnancy Trial Groups; MD, Mean difference; *OGTT*, oral glucose tolerance test; *RR*, relative risk; *STAI-SF*, State Trait Anxiety Inventory Score-Short Form.

[a] Adjusted for maternal baseline BMI; [b] Adjusted for gestational age at 36 weeks.

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TABLE 4
Neonatal primary and secondary outcomes of liveborn infants

Outcomes	Dietary intervention N = 116	Routine dietary advice N = 114	Adjusted treatment effect* RR or MD (95% CI)	*P* value	Probiotic N = 115	Placebo N = 115	Adjusted treatment effect* RR or MD (95% CI)	*P* value
Primary outcome								
Birthweight, g[a]	3575 (609) N = 111	3612 (646) N = 111	−24 (−146, 97)	.69	3685 (565) N = 110	3504 (672) N = 112	107 (−14, 228)	.08
Secondary outcomes								
Gestation, wk	39.1 (1.9) N = 111	39.1 (2.1) N = 111	−0.04 (−0.58, 0.49)	.87	39.3 (1.7) N = 110	38.9 (2.3) N = 112	0.48 (−0.05, 1.01)	.08
Gestation <37 wk, n/N (%)	10/111 (9.0)	4/111 (3.6)	2.59 (0.85–7.90)	.10	5/110 (4.6)	9/112 (8.0)	0.58 (0.20–1.65)	.31
NICU admission, n/N (%)	13/110 (11.8)	7/110 (6.4)	1.76 (0.72–4.31)	.21	8/109 (7.3)	12/111 (10.8)	0.69 (0.29–1.62)	.39
Composite morbidity, n/N (%)	17/111 (15.3)	13/111 (11.7)	1.24 (0.64–2.41)	.52	12/110 (10.9)	18/112 (16.1)	0.69 (0.35–1.34)	.27
Birth size measures	N = 111	N = 111			N = 110	N = 112		
Head circumference, cm	35.5 (1.6) N = 110	35.3 (2.1) N = 111	0.16 (−0.32, 0.64)	.51	35.5 (1.6) N = 109	35.2 (2.1) N = 112	0.35 (−0.12, 0.83)	.15
Length, cm	50.8 (2.8) N = 109	51.1 (3.4) N = 111	−0.35 (−1.18, 0.48)	.41	51.3 (2.9) N = 109	50.7 (3.3) N = 111	0.71 (−0.11, 1.53)	.09
Chest circumference, cm[b]	34.7 (2.0) N = 92	34.9 (2.2) N = 92	0.12 (−0.38, 0.62)	.65	35.0 (1.9) N = 95	34.6 (2.3) N = 89	0.24 (−0.25, 0.73)	.34
Left arm circumference, cm[b]	11.3 (1.3) N = 92	11.4 (1.4) N = 92	0.04 (−0.34, 0.43)	.82	11.3 (1.5) N = 95	11.4 (1.2) N = 89	−0.20 (−0.58, 0.18)	.30
Abdominal circumference, cm[b]	33.1 (2.3) N = 92	33.6 (2.5) N = 92	0.00 (−0.60, 0.59)	.99	33.5 (2.3) N = 95	33.1 (2.5) N = 89	0.20 (−0.39, 0.78)	.51
Birth size z scores	N = 111	N = 111			N = 110	N = 112		
Birthweight	0.59 (0.97)	0.63 (1.04)	−0.02 (−0.29, 0.24)	.86	0.72 (0.97)	0.50 (1.04)	0.26 (−0.00, 0.52)	.05
Head circumference	1.15 (1.12)	1.08 (1.13)	0.10 (−0.19, 0.40)	.50	1.14 (1.06)	1.09 (1.19)	0.11 (−0.19, 0.40)	.48
Length	0.51 (1.09)	0.69 (1.22)	−0.18 (−0.49, 0.14)	.27	0.66 (1.16)	0.54 (1.15)	0.15 (−0.16, 0.46)	.33
Birthweight centiles	N = 111	N = 111			N = 110	N = 112		
SGA <10th customized, n (%)	14 (12.6)	11 (9.9)	*P* = .81		8 (7.3)	17 (15.2)	*P* = .13	

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TABLE 4
Neonatal primary and secondary outcomes of liveborn infants *(continued)*

Outcomes	Dietary intervention N = 116	Routine dietary advice N = 114	Adjusted treatment effect* RR or MD (95% CI)	*P* value	Probiotic N = 115	Placebo N = 115	Adjusted treatment effect* RR or MD (95% CI)	*P* value
AGA 10-90th customized, n (%)	84 (75.7)	86 (77.5)			90 (81.8)	80 (71.4)		
LGA >90th customized, n (%)	13 (11.7)	14 (12.6)			12 (10.9)	15 (13.4)		
SGA <10th WHO, n (%)	4 (3.6)	4 (3.6)		.89	3 (2.7)	5 (4.5)		.78
AGA 10th-90th WHO, n (%)	79 (71.2)	82 (73.9)			81 (73.6)	80 (71.4)		
LGA >90th WHO, n (%)	28 (25.2)	25 (22.5)			26 (23.6)	27 (24.1)		
Whole-body composition (Pea Pod)[b]	N = 49	N = 61			N = 57	N = 53		
Fat mass, kg[b]	0.40 (0.21)	0.43 (0.22)	0.00 (−0.08, 0.07)	.93	0.40 (0.18)	0.44 (0.24)	−0.07 (−0.14, 0.01)	.09
Lean mass, kg[b]	3.1 (0.39)	3.1 (0.47)	0.01 (−0.11, 0.13)	.84	3.1 (0.43)	3.1 (0.43)	0.01 (−0.11, 0.12)	.88
Fat mass adjusted for lean mass, kg		—	0.00 (−0.08, 0.07)	.90	—	—	−0.07 (−0.14, 0.01)	.08
Skinfold measurements	N = 90	N = 89			N = 92	N = 87		
Subscapular, mm[b]	5.7 (1.3)	5.9 (1.4)	−0.08 (−0.48, 0.31)	.68	5.7 (1.3)	5.8 (1.4)	−0.22 (−0.61, 0.17)	.27
Triceps, mm[b]	6.3 (1.4)	6.4 (1.5)	−0.02 (−0.44, 0.41)	.94	6.3 (1.4)	6.4 (1.4)	−0.13 (−0.55, 0.28)	.53
Supra-iliac, mm[b]	5.7 (1.9)	5.9 (1.7)	−0.03 (−0.57, 0.51)	.90	6.0 (2.0)	5.7 (1.6)	0.11 (−0.42, 0.65)	.68
Arm muscle area, cm^2[c]	7.0 (1.8)	7.2 (1.9)	−0.22 (−0.75, 0.31)	.41	7.1 (2.0)	7.2 (1.6)	0.23 (−0.32, 0.78)	.41

Data are n/N (%), mean (SD), or RR.

Composite morbidity includes birth trauma (fracture, brachial plexus injury, cephalohematoma, subgaleal hematoma), hypoxic–ischemic encephalopathy, sepsis, respiratory distress requiring positive pressure support, and hypoglycemia requiring dextrose treatment.

All analyses adjusted for maternal body mass index at pregnancy booking, maternal ethnicity, and infant sex.

Interaction test for primary neonatal outcome P = .48.

AGA, appropriate for gestational age, birthweight >10th to < 90th centile; *CI*, confidence interval; *LGA*, large for gestational age, >90th centile; *MD*, mean difference; *NICU*, neonatal intensive care unit; *RR*, relative risk; *SD*, standard deviation; *SGA*, small for gestational age, birthweight <10th centile; *WHO*, World Health Organization.

[a] Birthweight additionally adjusted for gestation length; other measures of birth size and body composition additionally adjusted for; [b] crown-heel or; [c] acromion-radiale length.

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high-deprivation population of pregnant women with obesity in New Zealand. Nevertheless, the dietary intervention was associated with lower total weight-gain, which may be clinically important if associated with longer term positive effects on maternal or infant health. Probiotic treatment does not appear to have any short-term benefit in this multiethnic population of pregnant women with obesity. ■

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