nature medicine

Supplementary information

https://doi.org/10.1038/s41591-024-03356-1

Reduced-energy diet in women with gestational diabetes: the dietary intervention in gestational diabetes DiGest randomized clinical trial

In the format provided by the authors and unedited

Supplementary Material

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List of Steering Committee Members

List of Data Monitoring & Safety Board Members

List of Investigators (Listed in alphabetical order by institution.)

List of Research Team Members

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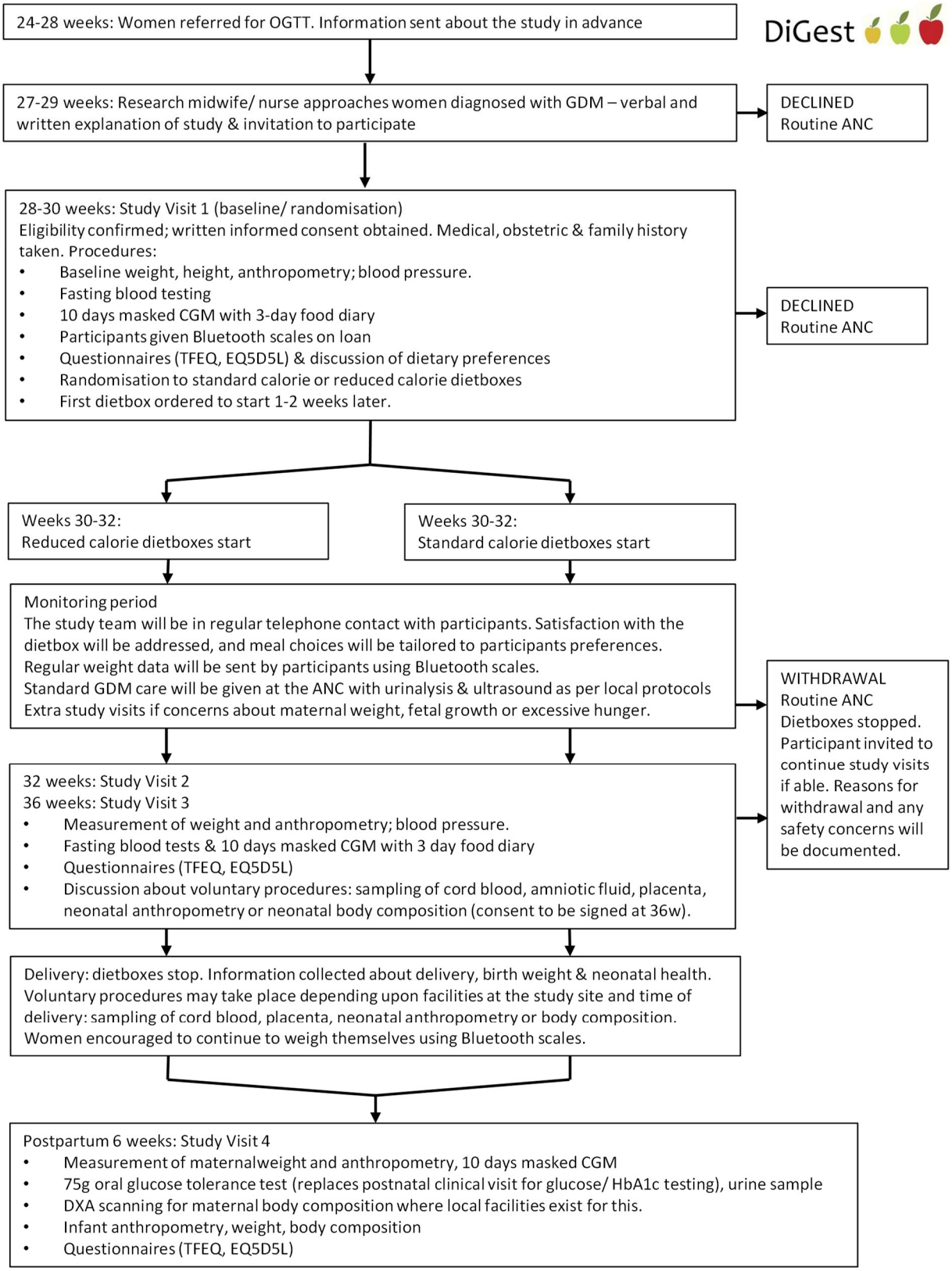
Definitions of Trial Outcomes

Supplementary Figure 1: The design of the DiGest randomized controlled trial.



Supplementary Table 1: Participant satisfaction with dietboxes in control and intervention groups. Results are summarised as n (%). Differences between intervention and control groups are reported as beta-coefficients (continuous outcomes). Regression models are adjusted for study centre. Data were collected by the food company (Mayfield) using an anonymous online questionnaire at Survey Monkey.

	Control	Intervention	Differences: Beta Coefficient (95% CI)	p
	n=214	n=211		
Completed satisfaction questionnaire on ≥1 occasion	68 (31.78%)	74 (35.07%)	-0.02 (-0.12, 0.08)	0.739
Completed satisfaction questionnaire from women who withdrew	30 (14.02%)	29 (13.74%)	0.02 (-0.19, 0.23)	0.838
Overall satisfaction score for quality of food				
% Highly satisfied	28 (41.18%)	27 (36.49%)		
% Satisfied	30 (44.12%)	33 (44.59 %)		
% Neither satisfied nor dissatisfied	6 (8.82%)	8 (10.81%)		
% Dissatisfied	4 (5.88%)	5 (6.76%)		
% Very dissatisfied	0 (0%)	1 (1.35%)		
Overall satisfaction score for quality of service				
% Highly satisfied	43 (65.15%)	43 (59.72%)		
% Satisfied	17 (25.76%)	26 (36.11%)		
% Neither satisfied nor dissatisfied	4 (6.06%)	3 (4.17%)		
% Dissatisfied	1 (1.52%)	0 (0%)		
% Very dissatisfied	1 (1.52%)	0 (0%)		

Supplementary table 2: Additional secondary outcomes, to fulfil requirements for the core outcomes set for diabetes in pregnancy

Core Outcomes	All Participants	Control	Intervention
Pre-eclampsia	**7/383**	**2/192**	**5/191**
Hypertensive disorders in pregnancy	**19/383**	**8/192**	**11/191**

Supplementary table 3: Effect of intervention upon maternal health-related quality of life (HR-QOL).

	Control	Intervention	Intervention effect (95% CI)	p
HR-QOL AT ENROLMENT	n=209	n=209		
Mobility	1.48 (0.71)	1.46 (0.69)		
Self-care	1.13 (0.40)	1.11 (0.36)		
Usual activity	1.47 (0.69)	1.50 (0.68)		
Pain	1.89 (0.84)	1.85 (0.74)		
Anxiety/depression	1.67 (0.87)	1.60 (0.77)		
Overall (HR-QOL index)	0.78 (0.19)	0.79 (0.16)		
HR-QOL AT 36 WEEKS	n=144	n=143		
Mobility	1.83 (0.91)	1.66 (0.83)	-0.08 (-0.26, 0.09)	0.34
Self-care	1.27 (0.56)	1.22 (0.50)	-0.01 (-0.13, 0.11)	0.88
Usual activity	1.84 (0.87)	1.66 (0.76)	-0.16 (-0.33, 0.003)	0.06
Pain	2.18 (0.81)	2.07 (0.76)	0.05 (-0.22, 0.11)	0.51
Anxiety/depression	1.56 (0.78)	1.50 (0.70)	-0.09 (-0.24, 0.06)	0.23
Overall (HR-QOL index)	0.72 (0.20)	0.75 (0.18)	0.02 (-0.01, 0.06)	0.25
HR-QOL AT 3 MONTHS POSTPARTUM	n=130	n=138		
Mobility	1.19 (0.47)	1.12 (0.39)	-0.06 (-0.16, 0.04)	0.26
Self-care	1.08 (0.39)	1.04 (0.25)	-0.03 (-0.11, 0.05)	0.44
Usual activity	1.19 (0.43)	1.15 (0.47)	-0.02 (-0.12, 0.09)	0.71
Pain	1.50 (0.73)	1.47 (0.71)	0.02 (-0.15, 0.18)	0.84
Anxiety/depression	1.61 (0.87)	1.48 (0.74)	-0.11 (-0.29, 0.06)	0.21
Overall (HR-QOL index)	0.86 (0.16)	0.88 (0.14)	0.01 (-0.03, 0.04)	0.69

Supplementary table 4: Number of participants who experienced weight loss or weight gain in the intervention and control arms

	Intervention	Control
Weight loss	85/214 (39.7%)	69/211 (32.7%)
Weight gain	113/214 (52.8%)	121/211 (57.3%)

Supplementary table 5: Baseline characteristics in women with HbA1c data available at both antenatal and postnatal timepoints in comparison to those with missing data. Data are represented as mean (SD) or n (%). Data also presented as median (IQR) are shown in bold.

	n	All Participants n=425	n	Participants with HbA1c at two timepoints n=63	n	Participants with missing data for HbA1c at one or more timepoints n=365	p
Maternal age years	425	33.03 (5.04)	63	33.64 (4.57)	365	32.96 (5.11)	0.26
BMI kg/m^2	425	35.67 (6.44)	63	36.20 (6.01)	365	35.55 (6.51)	0.83
Self-reported ethnicity	425		63		365		0.42
White		332 (78.12)		50 (79.37)		284 (77.81)	
Asian		73 (17.18)		8 (12.70)		66 (18.08)	
Black		17 (4.00)		4 (6.35)		13 (3.56)	
Other ethnic groups		3 (0.71)		1 (1.59)		2 (0.55)	
Primiparous	385	224 (52.68)	62	37 (59.68)	324	213 (65.74)	0.62
Gestational weight gain pre-enrolment kg	424	3.94 (5.89)	63	3.88 (5.86)	364	4.03 (5.97)	0.44
Maternal education (≥degree)	425	201 (47.29)	63	35 (55.56)	364	168 (46.03)	0.02
Index of Multiple Deprivation decile	412	6.53 (2.47)	63	6.73 (2.60)	349	6.49 (2.44)	0.12
Gestational diabetes in previous pregnancy	424	122 (28.77)	63	16 (25.40)	364	107 (29.40)	0.50
Health at Enrolment							
Smoking	422	44 (10.43)	61	2 (3.28)	364	43 (11.81)	0.017
Physical activity PAEE (kJ/kg/d)	230	19.86 (12.65)	34	18.96 (14.79)	196	20.03 (12.28)	0.86
Habitual energy intake kcal/day	215	1567.75 (653.40)	34	1658.60 (725.60)	181	1550.69 (639.68)	0.31
Basal Metabolic Rate J/(h/kg)	385	1643.07 (227.58)	62	1668.30 (214.40)	324	1637.56 (224.87)	0.66
Systolic blood pressure mmHg	418	115.69 (12.47)	59	112.97 (12.33)	362	116.13 (12.43)	0.27
Diastolic blood pressure mmHg	418	69.29 (10.12)	59	67.88 (10.79)	362	69.51 (9.96)	0.72
Diagnosis							
Gestational age at diagnosis	414	22.85 (6.40)	63	20.47 (8.37)	354	23.32 (5.89)	0.006
OGTT 0 hr glucose mmol/l	206	5.01 (0.71)	17	5.11 (0.90)	190	5.00 (0.69)	0.18
OGTT 2 hr glucose mmol/l	207	8.11 (1.67)	16	8.46 (2.04)	192	8.07 (1.63)	0.54
HbA1c mmol/mol	147	39.00 (4.63)	63	38.78 (5.26)	84	39.17 (4.11)	0.42
HbA1c %	147	5.72 (0.42)	63	5.70 (0.48)	84	5.74 (0.38)	0.42
Medication Use at Enrolment							
Metformin	425	94 (22.12)	63	16 (25.40)	365	79 (21.64)	0.89
Short-acting insulin	425	38 (8.94)	63	9 (14.29)	365	29 (7.95)	0.55

Long-acting insulin	425	101 (23.76)	63	25 (39.68)	365	76 (20.82)	0.037

	n	**All Participants n=425**	**n**	**Participants with HbA1c at two timepoints n=63**	**n**	**Participants with missing data for HbA1c at one or more timepoints n=365**	
GLYCAEMIA AT ENROLMENT							
Days of CGM use	361	5.79 (2.24)	54	6.10 (2.17)	308	5.73 (2.25)	0.22
Mean CGM glucose mmol/l	361	5.77 (0.77)	54	5.70 (0.76)	308	5.78 (0.77)	0.45
Mean CGM glucose mg/dl	361	103.95 (13.89)		102.77 (13.73)	308	104.10 (13.94)	0.45
TIR (3.5-6.7 mmol/l) %	361	77.02 (18.40) **83.30 (70.95 – 89.16)**	54	77.92 (18.85) **85.09 (75.98-89.16)**	308	76.92 (18.35) **83.22 (70.79-89.37)**	0.56
TAR (3.5-6.7 mmol/l) %	361	21.32 (19.18) **15.05 (7.87-28.61)**	54	20.33 (19.46) **12.90 (8.33-22.19)**	308	21.43 (19.16) **15.28 (7.83-28.78)**	0.56
TBR (3.5-6.7 mmol/l) %	361	1.66 (2.91) **0.53 (0.00-1.81)**	54	1.75 (2.01) **0.84 (0.17-3.07)**	308	1.65 (3.03) **0.49 (0.00-1.71)**	0.82
TIR (3.5-7.8 mmol/l) %	361	90.80 (10.98) **94.46 (88.79 – 97.31)**	54	90.72 (11.72) **94.21 (90.37-97.26)**	308	90.83 (10.85) **94.51 (88.36-97.31)**	0.81
TAR (3.5-7.8 mmol/l) %	361	7.54 (11.30) **3.20 (1.17-8.91)**	54	7.53 (12.06) **3.01 (1.04-6.56)**	308	7.52 (11.18) **3.23 (1.18-8.95)**	0.77
TBR (3.5-7.8 mmol/l) %	361	1.66 (2.91) **0.53 (0.00-1.81)**	54	1.75 (2.01) **0.84 (0.17-3.07)**	308	1.65 (3.03) **0.49 (0.00-1.71)**	0.82
CV	361	18.22 (3.84)	54	18.48 (4.28)	308	18.16 (3.76)	0.89
SD	361	1.05 (0.29)	54	1.06 (0.34)	308	1.05 (0.28)	0.89

Supplementary Table 6: Comparison of weight gain, weight loss and weight stable groups

The safety of weight loss in pregnancy: associations between weight loss, weight stability and weight gain upon maternal glycaemia and pregnancy outcomes. Weight loss was defined as weight loss of >1kg from enrolment to 36 weeks' gestation. Weight gain was defined as weight gain of >1kg from enrolment to 36 weeks' gestation. The weight stable group was defined as weight loss of < +/- 1kg from enrolment to 36 weeks' gestation. Results are summarised as mean and SD or median IQR (bold font). For continuous outcomes, intervention effect is the baseline (where available)-adjusted difference in mean outcome between intervention and control groups, estimated from a linear regression model that also includes study centre. For binary outcomes, intervention effect is the odds ratio comparing intervention vs control groups, estimated from a logistic regression model that also includes study centre. P-values <0.05 are considered statistically significant and the confidence intervals are two-sided. CGM: continuous glucose monitoring; GROW: gestation-related optimal weight centiles; NICU: neonatal intensive care unit; TIR: time in range. The number of subjects in this analysis (n=390) is smaller than that given in table 3. Participants could not be included if they had no weight data at 36 weeks' gestation. Outcomes which ended the pregnancy before 36 weeks could not be included, such as stillbirth, neonatal death and maternal death

	n	Weight stable n=92	n	Weight Loss n=119	n	Weight gain n=179	Differences Weight loss vs weight stable Ref: Weight stable	p	Differences Weight gain vs weight stable Ref: Weight stable	p	Differences Weight gain vs Weight loss Ref: Weight gain	p
Maternal age years	92	33.07 (4.02)	119	33.86 (4.99)	179	32.45 (5.35)	0.78 (-0.59, 2.14)	0.27	-0.76 (-2.03, 0.51)	0.24	1.54 (0.35, 2.72)	0.011
BMI kg/m²	92	34.65 (5.59)	119	37.50 (6.40)	179	34.75 (6.43)	2.83 (1.15, 4.50)	0.001	0.56 (-0.99, 2.11)	0.48	2.27 (0.82, 3.71)	0.002
Weight at enrolment kg	92	92.28 (16.51)	119	101.41 (20.74)	179	92.89 (20.07)	8.99 (3.73, 14.24)	0.001	2.02 (-2.85, 6.89)	0.42	6.97 (2.43, 11.52)	0.003
Self-reported ethnicity	92		119		179			0.33		0.034		<0.001
White		74 (80.43)		103 (86.55)		127 (70.95)						
Asian		13 (14.13)		9 (7.56)		45 (25.14)						
Black		3 (3.26)		6 (5.04)		7 (3.91)						
Other ethnic groups		2 (2.17)		1 (0.84)		0 (0.00)						
Primiparous	90	29 (32.22)	114	74 (64.91)	158	62 (39.24)	OR; 1.18 (0.65, 2.15)	0.58	OR; 1.45 (0.83, 2.54)	0.19	OR; 0.81 (0.49, 1.36)	0.43

Gestational weight gain pre-enrolment kg	92	3.82 (4.74)	119	3.83 (6.77)	178	4.24 (5.96)	-0.18 (-1.81, 1.44)	0.83	0.50 (-1.01, 2.00)	0.52	-0.68 (-2.08, 0.73)	0.34
Maternal education (≥degree)	92	48 (52.17)	119	59 (49.58)	179	85 (47.49)	OR; 0.87 (0.50, 1.53)	0.64	OR; 0.73 (0.43, 1.22)	0.23	OR; 1.20 (0.74, 1.96)	0.45
Index of Multiple Deprivation decile	88	6.46 (2.57)	116	6.72 (2.39)	173	6.71 (2.37)	0.27 (-0.37, 0.91)	0.41	-0.03 (-0.62, 0.57)	0.93	0.30 (-0.25, 0.84)	0.29
Gestational diabetes in previous pregnancy	91	31 (34.07)	119	27 (22.69)	179	54 (30.17)	OR; 0.54 (0.29, 1.02)	0.06	OR; 0.77 (0.44, 1.34)	0.36	0.70 (0.40, 1.23)	0.21
Neonatal Primary Outcome												
Standardised birthweight (Intergrowth)	89	0.39 (0.84) 0.37 (-0.09 – 1.03)	114	0.40 (0.91) 0.37 (-0.17 – 0.97)	157	0.54 (1.03) 0.64 (-0.05 – 1.21)	-0.02 (-0.29, 0.24)	0.87	0.17 (-0.08, 0.42)	0.18	-0.20 (-0.43, 0.04)	0.10
Birthweight g	89	3228.76 (461.08)	114	3288.53 (446.84)	158	3325.23 (471.89)	51.08 (-78.69, 180.84)	0.44	100.18 (-21.32, 221.467	0.11	-49.10 (-163.10, 64.90)	0.40
Birthweight Intergrowth centile	89	61.80 (25.48)	114	61.26 (25.69)	157	65.29 (27.88)	-1.22 (-8.68, -6.24)	0.75	4.07 (-2.93, 11.07)	0.25	-5.29 (-11.85, 1.28)	0.11
Neonatal Secondary Outcomes												
Large for gestational age Intergrowth	89	15 (16.85)	114	17 (14.91)	157	38 (24.20)	OR; 0.71 (0.32, 1.56)	0.40	OR; 1.69 (0.85, 3.34)	0.13	OR; 0.42 (0.21, 0.83)	0.012
Large for gestational age GROW	89	6 (6.74)	114	7 (6.14)	158	16 (10.13)	OR; 0.84 (0.27, 2.67)	0.77	OR; 1.74 (0.64, 4.72)	0.28	OR; 0.49 (0.19, 1.27)	0.14
NICU admission	88	11 (12.50)	114	9 (7.89)	159	14 (8.81)	OR; 0.52 (0.20, 1.38)	0.19	OR; 0.66 (0.28, 1.55)	0.34	OR; 0.79 (0.31, 2.00)	0.62

Estimated Gestational age at birth weeks	89	38.31 (1.45)	114	38.62 (1.30)	159	38.43 (1.19)	0.35 (-0.003, 0.71))	0.05	0.09 (-0.24, 0.43)	0.58	0.26 (-0.05, 0.58)	0.10
Cord blood C-peptide umol/l	22	271.27 (188.63)	34	256.77 (193.28)	41	283.20 (225.09)	-14.36 - 126.49, 97.76)	0.80	1.35 (-105.30, 107.99)	0.98	-15.71 (-110.98, 79.55)	0.74
Maternal Primary Outcome												
Weight change kg	92	0.08 (0.54)	119	-3.74 (3.79)	179	3.51 (2.79)	-3.74 (-4.49, -2.98)	<0.001	3.45 (2.75, 4.15)	<0.001	-7.19 (-7.85, -6.54)	<0.001
Weight at 36 weeks kg	92	92.36 (16.39)	119	97.70 (20.04)	179	96.40 (20.78)	-3.65 (-4.42, -2.89)	<0.001	3.48 (2.78, 4.17)	<0.001	-7.13 (-7.79, -6.47)	<0.001
Maternal Pregnancy Outcomes												
Caesarean section	92	40 (43.48)	119	47 (39.50)	179	81 (45.25)	OR; 0.82 (0.47, 1.44)	0.49	OR; 1.15 (0.69, 1.93)	0.59	OR; 0.71 (0.44, 1.16)	0.17
Metformin at 36 weeks	72	20 (27.78)	95	37 (38.95)	138	29 (21.01)	OR; 1.10 (0.48, 2.50)	0.82	OR; 0.51 (0.22, 1.18)	0.12	OR; 2.14 (1.00, 4.58)	0.05
Short-acting insulin at 36 weeks	72	12 (16.67)	95	9 (9.47)	138	20 (14.49)	OR; 0.36 (0.12, 1.13)	0.08	OR; 0.29 (0.10, 0.89)	0.030	OR; 1.25 (0.38, 4.05)	0.71
Long-acting insulin at 36 weeks	73	24 (32.88)	95	29 (30.53)	138	51 (36.96)	OR; 0.99 (0.42, 2.34)	0.99	OR; 1.11 (0.50, 2.50)	0.79	OR; 0.89 (0.43, 1.85)	0.75
TIR (3.5-6.7 mmol/l) at 36 weeks %	55	76.15 (19.39)	77	79.52 (16.19)	92	70.56 (18.73)	3.66 (-2.13, 9.44)	0.21	-2.57 (-8.23, 3.09)	0.37	6.23 (1.09, 11.36)	0.018
TIR (3.5-7.8 mmol/l) at 36 weeks %	55	90.75 (10.01)	77	92. 95 (7.38)	92	86.69 (12.59)	1.98 (-1.36, 5.32)	0.24	-2.75 (-6.01, 0.51)	0.10	4.73 (1.77, 7.69)	0.002
CGM mean glucose at 36 weeks mmol/l	55	5.77 (0.81)	77	5.66 (0.69)	92	5.95 (0.85)	-0.16 (-0.41, 0.09)	0.21	0.02 (-0.23, 0.26)	0.88	-0.18 (-0.41, 0.04)	0.10

CGM mean glucose at 36 weeks mg/dL	55	103.92 (14.59)	77	101.94 (12.47)	92	107.21 (15.34)	-2.90 (- 7.43, 1.63)	0.21	0.35 (-4.07, 4.77)	0.88	-3.31 (-7.31, 0.69)	0.10
Systolic blood pressure mmHg	76	117.91 (11.81)	99	116.42 (12.50)	141	119.77 (72.55)	-1.39 (-4.83, 2.05)	0.43	2.38 (-0.78, 5.54)	0.14	-3.70 (-6.70, -0.70)	0.016
Diastolic blood pressure mmHg	76	72.91 (11.81)	99	70.18 (10.25)	141	72.55 (10.64)	-2.17 (- 4.93, 0.59)	0.12	0.28 (-2.28, 2.84)	0.83	-2.41 (-4.82, -0.01)	0.05
Maternal Postnatal Outcomes at 3 months												
HbA1c mmol/mol	59	36.76 (3.82)	79	36.23 (3.59)	98	37.20 (4.43)	-2.94 (-5.53, -0.35)	0.027	0.43 (-2.43, 3.29)	0.76	-3.37 (-6.03, -0.71)	0.014
HbA1c %	59	5.52 (0.35)	79	5.47 (0.33)	98	5.56 (0.41)	-0.27 (-0.51, -0.03)	0.027	0.04 (-0.22, 0.30)	0.76	-0.31 (-0.55, -0.07)	0.014
TIR (3.9-10.0 mmol/l) %	40	98.07 (3.16)	68	98.05 (3.08)	80	96.22 (6.61)	-0.15 (-2.30, 1.99)	0.89	-1.73 (-3.81, 0.36)	0.10	1.57 (-0.21, 3.35)	0.08
CGM mean glucose mmol/l	40	6.21 (0.58)	68	6.26 (0.67)	80	6.32 (0.87)	0.09 (-0.22, 0.39)	0.57	0.07 (-0.23, 0.36)	0.66	0.02 (-0.23, 0.27)	0.87
CGM mean glucose mg/dL	40	111.81 (10.48)	68	112.70 (12.10)	80	113.94 (15.69)	1.58 (-3.92, 7.07)	0.57	1.21 (-4.13, 6.55)	0.66	0.37 (-4.18, 4.91)	0.87
Maternal weight kg	63	84.54 (16.03)	82	91.79 (18.15)	104	86.90 (20.00)	-1.97 (-3.91, -0.03)	0.047	2.35 (0.54, 4.16)	0.011	-4.32 (-6.05, -2.60)	<0.001
Maternal weight change from enrolment to 3 months	63	-6.19 (5.34)	82	-8.54 (6.33)	104	-3.90 (5.41)	-2.20 (-4.10, -0.29)	0.024	2.33 (0.53, 4.15)	0.012	-4.53 (-6.23, -2.84)	<0.001
Maternal BMI kg/m2	63	31.60 (5.27)	82	33.71 (6.06)	104	32.71 (6.89)	-0.72 (-1.43, -0.02)	0.046	0.87 (0.21, 1.54)	0.010	-1.60 (-2.23, -0.97)	<0.001
Maternal BMI change from enrolment to 3 months	63	-2.32 (-10.44, 1.6)	82	-3.16 (-15.71, 1.83)	104	-1.48 (-9.38, 4.08)	-0.78 (-1.50, -0.07)	0.032	0.87 (0.20, 1.55)	0.012	-1.65 (-2.29, 1.02)	<0.001
Systolic blood pressure mmHg	60	116.45 (13.36)	78	119.91 (13.38)	97	119.24 (14.41)	5.16 (0.93, 9.40)	0.017	3.37 (-0.64, 7.38)	0.10	1.79 (-1.97, 5.56)	0.35
Diastolic blood pressure mmHg	60	80.57 (15.40)	78	80.00 (13.30)	97	79.30 (11.17)	0.80 (-3.44, 5.04)	0.71	-1.20 (-5.22, 2.81)	0.56	2.00 (-1.77, 5.78)	0.30

SAFETY OUTCOMES						
Small for gestational age Intergrowth	89	2(2.25)	114	3 (2.63)	157	10 (6.37)
Stillbirth	92	0 (0.00)	119	0 (0.00)	179	0 (0.00)
Neonatal death	92	0 (0.00)	119	0 (0.00)	179	0 (0.00)
Maternal death	92	0 (0.00)	119	0 (0.00)	179	0 (0.00)
Congenital anomaly^	88	0 (0.00)	114	1 (0.88)	158	1 (0.63)

^ In the weight gain group: bilateral blepharoptosis. In the weight loss group: congenital haemangioma.

Supplementary table 7: Food menu for participants. All individual meals and each complete snack pack contained 40% energy from carbohydrate, 35% from fat and 25% from protein. An additional vegetable/salad pack was provided if requested which added an additional 20-30 kcal per day and used seasonal ingredients.

Breakfast (1 per day)	Main meals (2 per day)	Additional Items
Cheese and Mushroom Omelette with rosti	Fish Goujons	Snack Packs (1 per day)
Cheese and Ham Omelette with rosti	Salmon with Lemon Puy Lentils	Typical contents:
Breakfast bun (with egg bacon and mushroom filling)	Moroccan Spiced Chicken Wrap	Several pieces of fruit
Porridge with Jam and nuts	Mushroom Stroganoff	Savoury snacks -nuts, boiled eggs, crisps, veg sticks, hummus
Granola	Roasted Vegetable Lasagne	Low sugar treat items – very dark chocolate, plain biscuit.
Cinnamon Porridge with Sunflower Seeds	Vegetarian Chilli	
Cherry and Almond Yoghurt	Vegetarian Bean Stew	
Blueberry Yoghurt	Vegetarian Spaghetti Bolognese	
Welsh Rarebit	Macaroni Cheese with Kale	
Seeded Bagel with Almond butter and Philadelphia	Aloo Mutter Paneer with Rice	Vegetable/ Salad Pack (1 per week)
Scrambled Tofu with potato rosti	Mexican Bean Enchilada	Typical contents:
Scrambled Tofu and mushroom Breakfast bun	Chickpea and Spinach Curry with Spiced Paneer	Mushroom
	Beef Lamb and Venison	Cauliflower
	Beef Madras	Courgette
	Chilli Con Carne	Broccoli
	Beef in Black Bean sauce	Carrot
	Venison Sausages in Red Wine	Little Gem
	Spaghetti Bolognese	Cucumber
	Lamb Curry (medium)	Carrot
	Tandoori Chilli Chicken	Celery
	Chicken Schnitzel	Baby Plum tomatoes
	Thai Red Chicken Curry (hot)	Spring Onions
	Chicken Korma	Radishes
	Chicken Tikka Masala	
	Roast Turkey Dinner	
	Sausage and Pasta Bake	
	Pork Dijon	

List of Trial Steering Committee (TSC) Members

Prof Roy Taylor, Chair, consultant diabetologist, expertise in achieving type 2 diabetes remission in DiRECT study

Dr Adrian Park, consultant in obesity medicine

Prof Gordon Smith, consultant obstetrician, expertise in prediction of suboptimal birth outcomes.

Prof Helen Murphy, consultant diabetologist, expertise in interventional studies in pregnancy

Prof Vern Farewell, statistician.

Dr Angela Flynn, Senior nutritional scientist, expertise in diet in pregnancy

Dr Pam Dyson, diabetes dietician, expertise in nutritional management of diabetes

Ms Yvonne Nickerson, patient representative.

Ms Kamini Shah, Head of research funding, Diabetes UK.

Claire Meek, chief investigator

Other TSC attendees:

Deborah Hughes (DH)

Joanne Brown (JB)

Danielle Jones (DJ)

Laura Kusinski (LK)

List of Data Monitoring & Safety Board Members

Dr Rebecca Cannings-John, statistician with expertise in women and children's health.

Prof Rebecca Reynolds, consultant diabetologist, expertise in obesity in pregnancy

Prof Fionnuala MacAuliffe, consultant obstetrician, expertise in diabetes in pregnancy

List of Investigators (Listed in alphabetical order by institution.)

Dr Claire Meek; Cambridge University Hospitals NHS Foundation Trust

Rabia Zill-E-Huma; East and North Hertfordshire NHS Trust Lister

Lauren Smith; Kettering General Hospital NHS Foundation Trust

Dr Helen Murphy; Norfolk and Norwich University Hospitals NHS Foundation Trust

Dr Erick Leyva Caraballo; North West Anglia NHS foundation Trust Hinchingbrooke

Dr Erick Leyva Caraballo; North West Anglia NHS foundation Trust Peterborough

Salman Kidwal; Queen Elizabeth Hospital Kings Lynn NHS Foundation Trust

Mr Phillip Donkor; The Princess Alexandra Hospital Trust Harlow

List of Research Team Members

Coralie Glenn-Samsun

Lauren Andrews

Deborah Hughes

Jodie Carpenter

Kimberley Morris

Danielle Jones

Laura Kusinski

Suzanne Smith

Patrycja Tobolska

Joanne Brown

Elizabeth Turner

Tara Lee

Matilda Matthews

Laura Harris

Jo Brown

Edwina Lee

Joanne Finn

Hollie Curgenven

Sarah Johnson

Parizade Raymond

Anna William

Bincy Kariyadil

Inclusion criteria (from protocol version 11; 23/9/2020)

- **Women with gestational diabetes diagnosed before 30+6 weeks' gestation using a standard clinical 75g OGTT in accordance with the guidelines of the National Institute of Health and Care Excellence (NICE)(37).**
- The NICE criteria state that the diagnosis of gestational diabetes will be made with one or more glucose concentrations during the OGTT of:
    - ≥5.6 mmol/l in the fasting state
    - ≥7.8 mmol/l 2 hours after 75g glucose(38).

- During periods when antenatal OGTTs are suspended due to the restrictions caused by the Sars-CoV-2 virus, diagnosis of gestational diabetes will be made according to the criteria laid down at:

  https://www.rcog.org.uk/globalassets/documents/guidelines/2020-07-10-guidance-for-maternal-medicine.pdf , namely HbA1c ≥ 39mmol/mol or Fasting Blood Glucose ≥ 5.6mmol/l or Random Blood Glucose ≥ 9mmol/l (para 3.2.2.1).

- **Overweight or obese (BMI ≥25 kg/m^2) at time of OGTT.**
- A ultrasound-confirmed viable singleton pregnancy
- Planned antenatal care at the same centre or a different study centre throughout their pregnancy (ie: not planning to move away from the region before delivery).

Exclusion criteria (from protocol version 11; 23/9/2020)

Women will be excluded if any of the following criteria apply:

- Evidence of multiple pregnancy on ultrasound
- Evidence of severe congenital anomaly on ultrasound
- Patient planning to terminate the pregnancy for any reason
- Significant pre-pregnancy diseases or comorbidities which increase risk in pregnancy, for example renal failure, severe liver disease, transplantation, cardiac failure, psychiatric conditions requiring in-patient admission (<1 year).
- Significant complications in the current pregnancy, such as threatened preterm labour, severe anaemia (Hb<8g/dl) or intra-uterine growth restriction (IUGR)
- Previous diagnosis of diabetes outside of pregnancy
- HbA1c at baseline of ≥48 mmol/mol.
- Medications at the time of the OGTT which may interfere with the results of the OGTT (for example, steroids, immunosuppressants, certain antipsychotics)
- Estimated fetal weight <10th percentile at diagnosis of gestational diabetes
- Maternal requirement for a highly specialised diet (e.g. vegan)
- Maternal severe food allergy, for example, a nut allergy causing anaphylaxis
- Weight loss of >5% pre-pregnancy weight during pregnancy, prior to 28 weeks.

Definitions of Trial Outcomes

Primary Outcomes:

Maternal weight change was defined as: weight at 36 weeks' gestation – weight at study enrolment (kg).

Neonatal standardised birthweight was calculated based on INTERGROWTH, but data are also presented as GROW customised centiles.

Selected Secondary Outcomes:

Large for gestational age was defined as birthweight $\geq 90^{th}$ centile for gestational age.

Small for gestational age was defined as birthweight $<10^{th}$ centile for gestational age.

Neonatal hypoglycaemia was defined as a low blood glucose requiring intravenous dextrose

Estimated gestational age at birth was based on ultrasound assessment of gestational age.

Maternal glycaemia on continuous glucose monitoring time in range was defined as 3.5 – 6.7 mmol/l (63-120 mg/dl)