Different types of dietary advice for women with gestational diabetes mellitus (Review)

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TABLE OF CONTENTS

Figure 1. Figure 2. 1 DISCUSSION	HEADER	1
BACKGROUND OBJECTIVES METHODS RESULTS Figure 1.	ABSTRACT	1
NEISCUITS Figure 1. Figure 2. DISCUSSION ACKNOWLEDGEMENTS REFERENCES CHARACTERISTICS OF STUDIES DATA AND ANAIYSES ANAJYSIS 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 1 Macrosomia (birthweight gerater than 4000 g). Analysis 1.2. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 2 Large-for-gestational age. Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Portariv vaginal birth. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Portariv vaginal birth. Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Portariv vaginal birth. Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Portariv vaginal birth. Analysis 1.7. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Portariv vaginal birth. Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Portariv vaginal birth. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Portariv vaginal birth. Analysis 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Portariv vaginal birth. Analysis 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Preterm birth (≈ 37 weeks' gestation). Analysis 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (≈ 37 weeks' gestation). Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth (≈ 37 weeks' gestation). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.3. Comparison 2 Low-GI di	PLAIN LANGUAGE SUMMARY	2
METHODS Figure 1.		3
Figure 1. Figure 2. DISCUSSION ALTHORS' CONCLUSIONS ACKNOWLEDGEMENTS REFERENCES ALAUTHORS' CONCLUSIONS ACKNOWLEDGEMENTS REFERENCES CHARACTERISTICS OF STUDIES DATA AND ANALYSES Analysis 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 1.2. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 3 Caesarean section. Analysis 1.4. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Normal vaginal birth. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Shormla vaginal birth. Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Shaml-for-gestational age. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (<a (g).="" 11="" 2="" 2.1="" 2.2="" 2.3="" 2.4="" 2.5="" 2.7="" 2.9="" 37="" 4000="" 6="" agent="" analysis="" birth.="" birthweight="" compariso<="" comparison="" diet="" diet,="" for="" g).="" gestation).="" greater="" high-fibre="" hyperglycaemia.="" hypoglycaemic="" insulin="" low-gi="" moderate-gi="" or="" oral="" outcome="" peterm="" required="" td="" than="" versus="" weeks=""><td>OBJECTIVES</td><td>5</td>	OBJECTIVES	5
Figure 1. Figure 2. DISCUSSION	METHODS	5
Figure 2. DISCUSSION 1 AUTHORS' CONCLUSIONS 1 ACKNOWLEDGEMENTS 1 ECHARACTERISTICS OF STUDIES 1 DATA AND ANALYSES 2 Analysis 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 1.2. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 3 Caesarean section. Analysis 1.4. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 4 Operative vaginal birth. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Normal vaginal birth. Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Normal vaginal birth. Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Normal vaginal birth. Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Normal vaginal birth. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 8 Small-for-gestational age. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 10 Racrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight) ≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 9 Weight gain dur	RESULTS	10
DISCUSSION ACKNOWLEDGEMENTS 1 REFERENCES 1 ACKNOWLEDGEMENTS 1 REFERENCES 2 Analysis 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 1 Macrosomia (birthweight greater than 4000 g). 4 Analysis 1.2. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). 4 Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 3 Caesarean section. 4 Analysis 1.4. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 4 Operative vaginal birth. 4 Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). 4 Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. 4 Analysis 1.7. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. 4 Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 8 Small-for-gestational age. 4 Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. 4 Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). 4 Analysis 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). 4 Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 11 Insulin or oral hypoglycaemic agent required for hyperglycaemia. 4 Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 4 Birthweight (g). 4 Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 4 Birthweight (g). 4 Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. 5 Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). 5 Analysis 2.9. Comparison 3 Low-GI diet versus high-fibre mode	Figure 1	12
ACKNOWLEDGEMENTS CHARACTERISTICS OF STUDIES DATA AND ANAINSES Analysis 1.1 Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 1.2 Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 2 Large-for-gestational age (birthweight 2 90th percentile for gestational age). Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 3 Caesarean section. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 4 Operative vaginal birth. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 5 Normal vaginal birth. Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks gestation). Analysis 2.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks gestation). Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 5 Romaler at birth (weeks). Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI	Figure 2	13
ACKNOWLEDGEMENTS REFERENCES 1 REFERENCES 1 Analysis 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 1.2. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 3 Caesarean section. Analysis 1.4. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 4 Operative vaginal birth. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 5 Normal vaginal birth. Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). Analysis 1.7. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight) give 1 (g). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm bir	DISCUSSION	17
REFERENCES CHARACTERISTICS OF STUDIES Analysis 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 1.2. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 3 Caesarean section. Analysis 1.4. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 4 Operative vaginal birth. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 5 Normal vaginal birth. Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 8 Small-for-gestational age. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.11. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 11 Insulin or oral hypoglycaemic agent required for hyperglycaemia. Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 4 Birthweight (g). Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.6. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 9 Weight gain during pregnancy (kg). Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 9 Ronderal index (kg/m3). Analysis 2.1. Comparis	AUTHORS' CONCLUSIONS	19
CHARACTERISTICS OF STUDIES Analysis 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 1.2. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 3 Caesarean section. Analysis 1.4. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Operative vaginal birth. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Sirthweight (g). Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Sirthweight (g). Analysis 1.7. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Sirthweight (g). Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.11. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks gestation). Analysis 2.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks gestation). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. 4 Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. 5 Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. 6 Analysis	ACKNOWLEDGEMENTS	19
DATA AND ANALYSES Analysis 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 1.2. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 3 Caesarean section. Analysis 1.4. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 4 Operative vaginal birth. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 5 Normal vaginal birth. Analysis 1.7. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 8 Small-for-gestational age. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.11. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 1.11. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight geater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.9. C		19
Analysis 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 1.2. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 3 Caesarean section. Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Normal vaginal birth. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Normal vaginal birth. Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 1.11. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 5 Gestational age at birth (weeks). Analysis 2.7. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. 50. Analysis 2.7. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Macrosomia age. Analysis 2	CHARACTERISTICS OF STUDIES	23
greater than 4000 g). Analysis 1.2. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 4 Operative vaginal birth. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Normal vaginal birth. Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). Analysis 1.7. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 8 Small-forestational age. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 1.11. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.7. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.9. Comparison 3 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.10. Comparison 3 L	DATA AND ANALYSES	38
Analysis 1.2. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 3 Caesarean section. Analysis 1.4. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 4 Operative vaginal birth. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 5 Normal vaginal birth. Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Normal vaginal birth. Analysis 1.7. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Brall-for-gestational age at birth. Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 8 Small-for-gestational age. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 2.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 11 Insulin or oral hypoglycaemic agent required for hyperglycaemia. Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 4 Birthweight (g). Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 4 Birthweight (g). Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 5 Gestational age at birth (weeks). Analysis 2.7. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.8. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestatio	Analysis 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 1 Macrosomia (birthweight	
(birthweight ≥ 90th percentile for gestational age). Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 3 Caesarean section. Analysis 1.4. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 4 Operative vaginal birth. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 5 Normal vaginal birth. Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). Analysis 1.7. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 8 Small-for-gestational age. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.11. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 2.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 11 Insulin or oral hypoglycaemic agent required for hyperglycaemia. Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 4 Birthweight (g). Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.6. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.7. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). Analysis 2.8. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome		41
Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 3 Caesarean section. Analysis 1.4. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 4 Operative vaginal birth. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 5 Normal vaginal birth. Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). Analysis 1.7. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 8 Small-for-gestational age. Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 8 Induction of labour. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (c 37 weeks gestation). Analysis 1.11. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (c 37 weeks gestation). Analysis 2.1. Comparison 2 Low-moderate GI food versus high-moderate food, Outcome 11 Insulin or oral hypoglycaemic agent required for hyperglycaemia. Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.6. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.10. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestationa	Analysis 1.2. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 2 Large-for-gestational age	
Analysis 1.4. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 4 Operative vaginal birth. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 5 Normal vaginal birth. Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). Analysis 1.7. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 8 Small-for-gestational age. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 2.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 11 Insulin or oral hypoglycaemic agent required for hyperglycaemia. Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 4 Birthweight (g). Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.6. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). Analysis 2.10. Comparison 3 Energy-restricte	(birthweight \geq 90th percentile for gestational age)	42
Analysis 1.4. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 4 Operative vaginal birth. Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 5 Normal vaginal birth. Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). Analysis 1.7. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 8 Small-for-gestational age. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 1.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 2.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 11 Insulin or oral hypoglycaemic agent required for hyperglycaemia. Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 4 Birthweight (g). Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.6. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). Analysis 2.10. Comparison 3 Energy-restricte	Analysis 1.3. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 3 Caesarean section	42
Analysis 1.5. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 5 Normal vaginal birth. Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). Analysis 1.7. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 8 Small-for-gestational age. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 1.11. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate food, Outcome 11 Insulin or oral hypoglycaemic agent required for hyperglycaemia. Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 5 Gestational age at birth (weeks). Analysis 2.6. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.7. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.8. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). Analysis 2.9. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 1 Fetal mortality. Analysis 3.1. Comparison 3 Energy-restr		43
Analysis 1.6. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g). Analysis 1.7. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Small-for-gestational age. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 1.11. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 2.1. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 11 Insulin or oral hypoglycaemic agent required for hyperglycaemia. Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 5 Gestational age at birth (weeks). Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.6. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.8. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). Analysis 2.10. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 10 Adherence to dietary intervention. Analysis 3.1. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 2 Macrosomia. Analysis 3.4. Comparison 3 E		44
Analysis 1.7. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth. Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 8 Small-for-gestational age. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 1.11. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 1.11. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 11 Insulin or oral hypoglycaemic agent required for hyperglycaemia. Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 4 Birthweight (g). Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 5 Gestational age at birth (weeks). Analysis 2.6. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.8. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 9 Weight gain during pregnancy (kg). Analysis 2.10. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 1 Fetal mortality. Analysis 3.1. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 2 Macrosomia. Analysis 3.2.		44
Analysis 1.8. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 8 Small-for-gestational age. Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour. Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 1.11. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 11 Insulin or oral hypoglycaemic agent required for hyperglycaemia. Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 4 Birthweight (g). Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.7. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.8. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 9 Weight gain during pregnancy (kg). Analysis 2.10. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 10 Adherence to dietary intervention. Analysis 3.1. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 1 Fetal mortality. Analysis 3.1. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 2 Macrosomia. Analysis 3.2. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 4 Caesarean section.		45
Analysis 1.9. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour		45
Analysis 1.10. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation). Analysis 1.11. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 11 Insulin or oral hypoglycaemic agent required for hyperglycaemia. Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 4 Birthweight (g). Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 5 Gestational age at birth (weeks). Analysis 2.6. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.7. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.8. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). Analysis 2.10. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 9 Weight gain during pregnancy (kg). Analysis 2.10. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 10 Adherence to dietary intervention. Analysis 2.11. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 1 Fetal mortality. Analysis 3.1. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 3 Large-for-gestational age. Analysis 3.3. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 4 Caesarean section.		46
Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 4 Birthweight (g). Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 5 Gestational age at birth (weeks). Analysis 2.6. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.7. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.8. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). Analysis 2.10. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 9 Weight gain during pregnancy (kg). Analysis 2.10. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 10 Adherence to dietary intervention. Analysis 2.10. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 1 Fetal mortality. Analysis 3.1. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 3 Large-for-gestational age. Analysis 3.3. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 4 Caesarean section.		
Analysis 1.11. Comparison 1 Low-moderate GI food versus high-moderate food, Outcome 11 Insulin or oral hypoglycaemic agent required for hyperglycaemia	, .	46
agent required for hyperglycaemia. Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g). Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age). Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section. Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 4 Birthweight (g). Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 5 Gestational age at birth (weeks). Analysis 2.6. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.7. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.8. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 9 Weight gain during pregnancy (kg). Analysis 2.10. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 10 Adherence to dietary intervention. Analysis 2.11. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 1 Fetal mortality. Analysis 3.1. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 2 Macrosomia. Analysis 3.3. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 4 Caesarean section.		
Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater than 4000 g)		47
than 4000 g)	Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 1 Macrosomia (birthweight greater	
Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age)		48
(birthweight ≥ 90th percentile for gestational age)		
Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section		48
Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 4 Birthweight (g)		49
Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 5 Gestational age at birth (weeks). Analysis 2.6. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth. Analysis 2.7. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age. Analysis 2.8. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 9 Weight gain during pregnancy (kg). Analysis 2.10. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 10 Adherence to dietary intervention. Analysis 2.11. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 11 Insulin required for hyperglycaemia. Analysis 3.1. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 1 Fetal mortality. Analysis 3.2. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 2 Macrosomia. Analysis 3.3. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 3 Large-for-gestational age. Analysis 3.4. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 4 Caesarean section.		49
Analysis 2.6. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth		50
Analysis 2.7. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-for-gestational age		50
Analysis 2.8. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3). 5 Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 9 Weight gain during pregnancy (kg)		51
Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 9 Weight gain during pregnancy (kg)	, 1	51
Analysis 2.10. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 10 Adherence to dietary intervention	Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 9 Weight gain during pregnancy	
Analysis 2.11. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 11 Insulin required for hyperglycaemia		
hyperglycaemia		52
Analysis 3.1. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 1 Fetal mortality 5 Analysis 3.2. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 2 Macrosomia 5 Analysis 3.3. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 3 Large-for-gestational age. Analysis 3.4. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 4 Caesarean section 5		
Analysis 3.2. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 2 Macrosomia 5 Analysis 3.3. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 3 Large-for-gestational age. Analysis 3.4. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 4 Caesarean section 5		53
Analysis 3.3. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 3 Large-for-gestational age. Analysis 3.4. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 4 Caesarean section. 5		53
Analysis 3.4. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 4 Caesarean section. 5		54
	, , ,	55
		55
Analysis 3.5. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 5 Operative vaginal birth.	Analysis 3.5. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 5 Operative vaginal birth.	56

Analysis 3.6. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 6 Normal vaginal birth.	57
Analysis 3.7. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 7 Induction of labour.	57
Analysis 3.8. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 8 Pre-eclampsia	58
Analysis 3.9. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 9 Insulin or oral hypoglycaemic	
agent required for hyperglycaemia.	59
Analysis 3.10. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 10 Insulin sensitivity.	60
Analysis 4.1. Comparison 4 Low-carbohydrate (CHO) diet (≤ 45% total energy from CHO) versus high-CHO diet (≥	
50% total energy from CHO), Outcome 1 Macrosomia (birthweight greater than 4000 g)	61
Analysis 4.2. Comparison 4 Low-carbohydrate (CHO) diet (≤ 45% total energy from CHO) versus high-CHO diet (≥	01
50% total energy from CHO), Outcome 2 Caesarean section.	61
Analysis 4.3. Comparison 4 Low-carbohydrate (CHO) diet (≤ 45% total energy from CHO) versus high-CHO diet (≥	01
50% total energy from CHO), Outcome 3 Operative vaginal birth.	62
Analysis 4.4. Comparison 4 Low-carbohydrate (CHO) diet (≤ 45% total energy from CHO) versus high-CHO diet (≥	02
50% total energy from CHO), Outcome 4 Normal vaginal birth	63
Analysis 4.5. Comparison 4 Low-carbohydrate (CHO) diet (\leq 45% total energy from CHO) versus high-CHO diet (\geq	03
	(2
50% total energy from CHO), Outcome 5 Birthweight (g)	63
Analysis 4.6. Comparison 4 Low-carbohydrate (CHO) diet (≤ 45% total energy from CHO) versus high-CHO diet (≥	
50% total energy from CHO), Outcome 6 Gestational age at birth (weeks).	64
Analysis 5.1. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO	,.
diet (≥ 50% total energy from CHO), Outcome 1 Macrosomia (birthweight greater than 4000 g)	65
Analysis 5.2. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO	
diet (≥ 50% total energy from CHO), Outcome 2 Large-for-gestational age	65
Analysis 5.3. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO	
diet (\geq 50% total energy from CHO), Outcome 3 Birthweight (g)	66
Analysis 5.4. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO	
diet (≥ 50% total energy from CHO), Outcome 4 Gestational age at birth (weeks)	66
Analysis 5.5. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO	
diet (≥ 50% total energy from CHO), Outcome 5 Pre-eclampsia	67
Analysis 5.6. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO	
diet (≥ 50% total energy from CHO), Outcome 6 Insulin or oral hypoglycaemic agent required for hyperglycaemia.	67
Analysis 5.7. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO	
diet (≥ 50% total energy from CHO), Outcome 7 Maternal weight at late pregnancy (third trimester) (kg)	68
Analysis 5.8. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO	
diet (≥ 50% total energy from CHO), Outcome 8 Maternal BMI at late pregnancy (third trimester) (kg/m2).	69
Analysis 5.9. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO	
diet (≥ 50% total energy from CHO), Outcome 9 Maternal postpartum BMI (> 4 months postpartum) (kg/m2).	70
Analysis 5.10. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-	
CHO diet (≥ 50% total energy from CHO), Outcome 10 Development of type 2 diabetes	71
Analysis 5.11. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-	
CHO diet (≥ 50% total energy from CHO), Outcome 11 Development of glucose intolerance without meeting type	
2 diabetes diagnostic criteria.	72
Analysis 6.1. Comparison 6 Standard ADA diet (20 g fibre/day) versus fibre-enriched diet (80 g fibre/ day), Outcome 1	
Birthweight (g).	73
Analysis 6.2. Comparison 6 Standard ADA diet (20 g fibre/day) versus fibre-enriched diet (80 g fibre/ day), Outcome 2	
Gestational age at birth (weeks).	73
Analysis 6.3. Comparison 6 Standard ADA diet (20 g fibre/day) versus fibre-enriched diet (80 g fibre/ day), Outcome 3	
Insulin or oral hypoglycaemic agent required for hyperglycaemia.	74
Analysis 6.4. Comparison 6 Standard ADA diet (20 g fibre/day) versus fibre-enriched diet (80 g fibre/ day), Outcome 4	
Gestational weight gain (kg).	74
APPENDICES	74
CONTRIBUTIONS OF AUTHORS	75
DECLARATIONS OF INTEREST	75
SOURCES OF SUPPORT	75

DIFFERENCES BETWEEN PROTOCOL AND REVIEW	75
INDEX TERMS	75

[Intervention Review]

Different types of dietary advice for women with gestational diabetes mellitus

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ABSTRACT

Background

Gestational diabetes mellitus (GDM) affects a significant number of women each year and is associated with a wide range of adverse outcomes for women and their babies. Dietary counselling is the main strategy in managing GDM, but it remains unclear which dietary therapy is best.

Objectives

To assess the effects of different types of dietary advice for women with GDM on pregnancy outcomes.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (17 May 2012) and the WOMBAT Perinatal Trials Registry (17 April 2012).

Selection criteria

Randomised controlled trials (RCTs) and cluster-RCTs assessing the effects of different types of dietary advice for women with GDM on pregnancy outcomes.

We intended to compare two or more forms of the same type of dietary advice against each other, i.e. standard dietary advice compared with individualised dietary advice, individual dietary education sessions compared with group dietary education sessions. We intended to compare different intensities of dietary intervention with each other, i.e. single dietary counselling session compared with multiple dietary counselling sessions.

Data collection and analysis

Two review authors independently assessed study eligibility, extracted data and assessed risk of bias of included studies. Data were checked for accuracy.

Main results

We included nine trials; 429 women (436 babies) provided outcome data. All nine included trials had small sample sizes with variation in levels of risk of bias. A total of 11 different types of dietary advice were assessed under six different comparisons, including:

low-moderate glycaemic index (GI) food versus high-moderate GI food,

low-GI diet versus high-fibre moderate-GI diet,

energy-restricted diet versus no energy restriction diet,

low-carbohydrate diet (≤ 45% daily total energy intake from carbohydrate) versus high-carbohydrate diet (≥ 50% daily total energy intake from carbohydrate),

high-monounsaturated fat diet (at least 20% total energy from monounsaturated fat) versus high-carbohydrate diet (at least 50% total energy from carbohydrate),

standard-fibre diet (American Diabetes Association (ADA) diet) (20 grams fibre/day) versus fibre-enriched diet (80 grams fibre/day).

In the low-moderate GI food versus moderate-high GI food comparison, no significant differences were seen for macrosomia or large-for-gestational age (LGA), (two trials, 89 babies) (risk ratio (RR) 0.45, 95% confidence interval (CI) 0.10 to 2.08), (RR 0.95, 95% CI 0.27 to 3.36), respectively; or caesarean section (RR 0.66, 95% CI 0.29 to 1.47, one trial, 63 women).

In the low-GI diet versus high-fibre moderate-GI diet comparison, no significant differences were seen for macrosomia or LGA (one trial, 92 babies) (RR 0.32, 95% CI 0.03 to 2.96), (RR 2.87, 95% CI 0.61 to 13.50), respectively; or caesarean section (RR 1.80, 95% CI 0.66 to 4.94, one trial, 88 women).

In the energy-restricted versus unrestricted diet comparison, no significant differences were seen for macrosomia (RR 1.56, 95% CI 0.61 to 3.94, one trial, 122 babies); LGA (RR 1.17, 95% CI 0.65 to 2.12, one trial, 123 babies); or caesarean section (RR 1.18, 95% CI 0.74 to 1.89, one trial, 121 women).

In the low- versus high-carbohydrate diet comparison, none of the 30 babies in a single trial were macrosomic; and no significant differences in caesarean section rates were seen (RR 1.40, 95% CI 0.57 to 3.43, one trial, 30 women).

In the high-monounsaturated fat versus high-carbohydrate diet comparison, neither macrosomia or LGA (one trial 27 babies) (RR 0.65, 95% CI 0.91 to 2.18), (RR 0.54 95% CI 0.21 to 1.37), respectively showed significant differences. Women having a high-monounsaturated fat diet had a significantly higher body mass index (BMI) at birth (mean difference (MD) 3.90 kg/m², 95% CI 2.41 to 5.39, one trial, 27 women) and at six to nine months postpartum (MD 4.10 kg/m², 95% CI 2.34 to 5.86, one trial, 27 women) when compared with those having a high-carbohydrate diet. However, these findings were based on a single, small RCT with baseline imbalance in maternal BMI.

Perinatal mortality was reported in only trial which recorded no fetal deaths in either the energy- restricted or unrestricted diet group.

A single trial comparing ADA diet (20 grams gram fibre/day) with fibre-enriched fibre enriched diet (80 grams gram fibre/day) did not report any of our prespecified primary outcomes.

Very limited data were reported on the prespecified outcomes for each of the six comparisons. Only one trial reported on early postnatal outcomes. No trial reported long-term health outcomes for women and their babies. No data were reported on health service cost or women's quality of life.

Authors' conclusions

Data for most comparisons were only available from single studies and they are too small for reliable conclusions about which types of dietary advice are the most suitable for women with GDM. Based on the current available evidence, we did not find any significant benefits of the diets investigated.

Further larger trials with sufficient power to assess the effects of different diets for women with GDM on maternal and infant health outcomes are needed. Outcomes such as longer-term health outcomes for women and their babies, women's quality of life and health service cost should be included.

PLAIN LANGUAGE SUMMARY

Different types of dietary advice for women with gestational diabetes mellitus

Each year, a significant number of pregnant women around the world develop gestational diabetes mellitus (GDM), defined as glucose intolerance or high blood glucose concentration (hyperglycaemia) that starts or is first recognised during pregnancy. Women with GDM are at risk of having instrumental birth and their babies are more likely to be large for gestational age, have a birthweight of at least 4000 grams and experience birth trauma. Although it is widely accepted that dietary counselling is the main strategy for managing women with GDM, it is not clear which dietary therapy is best. The aim of this review was to assess the effects of different types of dietary advice for women with GDM looking at pregnancy outcomes. A total of nine small randomised trials involving 437 women (444 babies), with outcome data available for 429 women and 436 babies were included in this review. Eleven different types of dietary advice were assessed within six different comparisons, including low- or moderate- glycaemic index (GI) diet compared with high- or mixed-GI diet, low-GI diet compared with high-fibre, moderate-GI diet, energy-restricted diet compared with no energy restriction diet, lowcarbohydrate diet compared with high-carbohydrate diet, high-monounsaturated fat diet compared with high-carbohydrate diet, and the standard American Diabetes Association diet providing 20 grams fibre per day compared with fibre-enriched diet providing 80 grams fibre per day. Based on the current available data, we did not find that any one type of dietary advice was more effective than others in reducing the number of births that required instrumental delivery or the number of babies who were large for gestational age or had a birthweight of 4000 grams or more. The included trials had various levels of risk of bias and it remains unclear which diet is the most suitable diet for women with GDM for improving the health of women and their babies in the short and longer term. Larger, well-designed randomised trials are needed.

BACKGROUND

Description of the condition

Introduction and definition of gestational diabetes mellitus

Although there is no universally accepted diagnostic criteria (Coustan 2010), gestational diabetes mellitus (GDM) can be defined as 'glucose intolerance or hyperglycaemia (high blood glucose concentration) with onset or first recognition during pregnancy' (ACOG 2001; Hoffman 1998; Metzger 1998; NICE 2008). It is one of the most common pregnancy complications, with about 1% to 14% of pregnancies affected every year around the world (Mulla 2010). The prevalence of GDM continues to increase in line with the increasing prevalence of maternal obesity and type 2 diabetes mellitus (T2DM) (Bottalico 2007; Dabelea 2005; Mulla 2010).

Pathophysiology of gestational diabetes mellitus

In pregnancy, insulin resistance increases with advancing gestation (Clapp 2006). Hormones secreted from the placenta, including tumour necrosis factor-alpha (TNF- α), placental lactogen, placental growth hormone, cortisol and progesterone are thought to be the likely triggers of these physiological changes (Clapp 2006;

Devlieger 2008). Increasing insulin resistance in pregnancy, especially during the third trimester, helps to meet the increased nutrient requirement for fetal development and promotes fetal growth by increasing maternal glucose supply (Devlieger 2008). GDM results when the insulin secretion is inadequate for the degree of insulin resistance (Clapp 2006).

Risk factors for gestational diabetes mellitus

A range of factors have been found to increase the risk of developing GDM (Morisset 2010). Advancing maternal age and maternal overweight (body mass index (BMI) equal to or greater than 25 kg/m²) or obesity (equal to or greater than 30 kg/m²) are the two most common risk factors (Morisset 2010). It is important to note that the prevalence of overweight or obesity is increasing worldwide, which is associated with increasing prevalence of GDM (Petry 2010).

High parity, non-white race/ethnicity, family history of diabetes mellitus, maternal high or low birthweight and polycystic ovarian syndrome are the known non-modifiable risk factors for GDM (Cypryk 2008; Petry 2010; Solomon 1997). The modifiable risk factors include history of having a macrosomic (birthweight 4000 grams or more) infant and history of GDM (Petry 2010). Other modifiable risk factors are lifestyle related, which include physical inactivity (Chasan-Taber 2008), having a low-fibre and high-glycaemic load diet (Zhang 2006), and excessive weight gain during pregnancy, especially for those who are overweight or obese (Hedderson 2010).

Health risks for gestational diabetes mellitus

Negative impacts of GDM on the health of women and their babies have been consistently reported (Crowther 2005; Landon 2009; Metzger 2008; Reece 2009).

Short-term risks for women with GDM include developing preeclampsia and increased need for induction of labour (Anderberg 2010; Crowther 2005; Dodd 2007; Ju 2008; Landon 2009; Metzger 2008) and caesarean section (Dodd 2007; Landon 2009; Metzger 2008). The incidence of cephalopelvic disproportion, uterine rupture, shoulder dystocia and perineal lacerations is increased in women with GDM due to the increased likelihood of having a large-for-gestational age (LGA) or macrosomic baby (Jastrow 2010). In the longer term, women who have a history of GDM have at least a seven-fold risk of developing T2DM in the future when compared with women who have had a normoglycaemic pregnancy (Bellamy 2009), and up to 50% of women with GDM will develop T2DM within 10 years of the index pregnancy (Kim 2002).

One of the most significant health risks for babies born to mothers with GDM is being LGA or macrosomic (Crowther 2005; Landon 2009; Metzger 2008; Reece 2009). Being a LGA fetus or macrosomic infant is a surrogate for many of the complications associated with GDM (Esakoff 2009). LGA or macrosomic infants are at increased risk of birth injury, such as shoulder dystocia, perinatal asphyxia, bone fractures and nerve palsies (Henriksen 2008; Langer 2005; Metzger 2008). Babies LGA at birth are more likely to be heavier at every age (adjusted for height) and to develop early overweight or obesity and T2DM (Pettitt 1993; Whincup 2008). In addition, babies born LGA are at increased risk of developing metabolic syndrome (a cluster of risk factors defined by the occurrence of three of the following: obesity, hypertension, hypertriglyceridaemia and low HDL cholesterol concentration) in childhood, adolescence or adulthood (Baker 1994; Guerrero-Romero 2010; Harder 2009). Development of the metabolic syndrome during childhood predicts adult T2DM at 25 to 30 years of age (Morrison 2008). These health problems repeat across generations (Mulla 2010; Petitt 1985).

Besides the risks relating to LGA or macrosomia, other perinatal risk factors for babies born to women with GDM include respiratory distress syndrome, hypoglycaemia, hyperbilirubinaemia (increased levels of bilirubin in the blood), cardiomyopathy (the deterioration of the function of the heart muscle layer), hypocalcaemia, hypomagnesaemia, polycythaemia (increase in the number of circulating red blood cells, hyperviscosity and admission to the neonatal nursery (Metzger 2008; Reece 2009; Soler 1978). Other longer-term risks for these babies include developing type 1 diabetes mellitus (Harder 2009) and having impaired neurobehavioural development (Rizzo 1997).

Management of gestational diabetes mellitus

The primary aims of management for GDM are to optimise glycaemic control and improve pregnancy outcomes (Alwan 2009; Kim 2010a). Providing dietary and lifestyle advice is usually recommended as the primary therapeutic strategy for women with GDM (ACOG 2001; Hoffman 1998; NICE 2008). If diet and lifestyle management alone are not enough to achieve good maternal glycaemic control, insulin therapy or oral hypoglycaemics such as glyburide and metformin may be indicated (ACOG 2001; Hoffman 1998; NICE 2008; Silva 2010; Simmons 2004). As a part of GDM management, maternal glucose monitoring and ultrasonography are advised to monitor treatment and to guide care for birth (ACOG 2001; Hoffman 1998; NICE 2008).

Description of the intervention

Dietary advice for managing gestational diabetes mellitus

Although it is widely accepted that diet therapy is the primary strategy for managing GDM, there is very little evidence on specific nutritional approaches such as total energy intake and nutrient distribution in GDM management (Cheung 2009; Kim 2010a; Metzger 2007). Elevated blood glucose concentrations, especially postprandial glucose elevations are associated with adverse pregnancy outcomes in GDM (De Veciana 1995). Dietary advice provided for women with GDM should ensure adequate nutrients for normal fetal growth and maternal health, but not induce weight loss or excessive weight gain during pregnancy; it also aims to assist optimal glycaemic control (ACOG 2001; Hoffman 1998; Metzger 2007; NICE 2008).

Total energy intake and weight gain during pregnancy

Given the high prevalence of overweight and obesity in women with GDM, dietary advice for appropriate pregnancy weight gain is always included as a part of nutritional management of GDM (Kim 2010a). It is estimated that the prevalence of GDM for women with a BMI within the range of 35 kg/m² to 64.9 kg/m² (extremely obese) is 15.4%, and decreases to 5.5%, 4.8% and 2.3% for women having a BMI within the ranges of 30 kg/m² to 34.9 kg/m² (obese), 25 kg/m² to 29.9 kg/m² (overweight) and 18.5 kg/m² to 24.9 kg/m² (normal weight), respectively (Kim 2010b). Small reductions in weight improve glycaemic control (ACOG 2005). However, severe calorie restriction and pregnancy weight loss are discouraged due to the risks of ketonaemia and small-for-gestational-age (SGA) infants (ACOG 2001; Hoffman 1998; NICE 2008).

In 2009, the Institute of Medicine released its new guidelines for weight gain during pregnancy, which are stratified by prepregnancy BMI, i.e. women with a pre-pregnancy BMI between 25 and 29.9 kg/m² should aim for 6.8 to 11.4 kg weight gain and

those with pre-pregnancy BMI of 30 kg/m² or more should aim for 5 to 9 kg weight gain (IOM 2009). However, the degree of energy restriction for pre-pregnancy overweight and obese women to achieve these weight gain goals is unknown (Kim 2010a).

The optional proportion of the total energy derived from each of the macronutrients in GDM management is still controversial (Kim 2010a). In Australia, the principles of dietary management of diabetes are also recommended for GDM management (i.e. carbohydrate contributes up to 50% total energy intake, fat accounts for less than 30% total energy and protein accounts for 10% to 20% total energy intake) (Colagiuri 2009; Hoffman 1998).

Carbohydrate and glycaemic index (GI)

Carbohydrate is an important source of energy, vitamins, minerals and fibre and is the main nutrient that affects blood glucose values (Reader 2007). Its impact on blood glucose concentrations can be affected by the total amount and type of carbohydrate (Reader 2007).

Evidence on the proportion in carbohydrate in diet therapy for GDM management is also controversial (Kim 2010a). Both lowcarbohydrate diets (i.e. carbohydrate accounts for less than 42% total energy intake) and high-carbohydrate diets (i.e. carbohydrate accounts for 55% total energy intake) have been found beneficial in improving pregnancy outcomes in non-randomised studies (Clapp 2002; Major 1998; Romon 2001). These inconsistent findings triggered the hypothesis that in addition to the total amount of carbohydrate, the type of carbohydrate may also be an important factor that affects postprandial blood glucose levels (Kim 2010a). GI is a ranking of the effects of carbohydrates on blood glucose concentrations (Jenkins 1981). Foods with a low GI (less than 55) produce a lower postprandial glucose elevation and area under the curve; foods with a high GI (more than 70) produce a rapid increase in postprandial blood glucose concentrations (Jenkins 1981). In non-pregnant people with diabetes, evidence shows that using low-GI diets helps lower HbA1C and gives better glycaemic control (Thomas 2010). During pregnancy, the concept of GI is still valid (Cheung 2009). Some evidence has suggested benefits of using low-GI diets in GDM management (Moses 2009).

Fat and other nutrients

Polyunsaturated fatty acids may be protective against impaired glucose tolerance, while saturated fatty acids can increase glucose and insulin concentrations in women with GDM (Ilic 1999). However, the specific amount and sources of fat that are beneficial for GDM management are not clear (Kim 2010a). Therefore, recommendations on the fat intake for women with GDM have not yet been promulgated (ACOG 2001; Hoffman 1998; Metzger 2007; NICE 2008).

Recommendations on the intake of other nutrients for women with GDM are usually based on the general recommendations for diabetes mellitus (Cheung 2009).

Why it is important to do this review

GDM affects a significant proportion of pregnant women each year and the prevalence is increasing worldwide (Bottalico 2007; Dabelea 2005; Mulla 2010). It is associated with a range of adverse pregnancy outcomes and these adverse health outcomes can repeat across generations (Metzger 2008; Mulla 2010). Dietary counselling is the primary therapeutic strategy in GDM management (Hoffman 1998; Metzger 2007; NICE 2008). However, there is much inconsistency and uncertainty around the best dietary therapies for women with GDM (Dornhorst 2002; Kim 2010a). This review will provide reliable evidence on the effects of different dietary advice for women with GDM for improving pregnancy outcomes. One Cochrane review has addressed the effects of different diets, including low-GI diet and high-fibre diet, in pregnancy for preventing GDM (Tieu 2008). Another Cochrane review has addressed the effects of different treatments for women with GDM (Alwan 2009). In Alwan 2009, diet and exercise advice for women with GDM was compared with pharmacological treatment, additional diet and exercise advice was compared with standard antenatal care and standard diet advice was compared with individualised diet advice for women with GDM, but they did not compare different types of dietary advice, as is done in this review.

OBJECTIVES

To assess the effects of different types of dietary advice given to women with gestational diabetes mellitus (GDM) in pregnancy outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

All published randomised controlled trials (RCTs) and cluster-randomised trials assessing the effects of different dietary advice for gestational diabetes mellitus (GDM) management. We intended to include published abstracts for RCTs and cluster-randomised trials if relevant outcome data were available. We planned to exclude quasi-RCTs and cross-over trials.

We planned to include trials assessing the effects of lifestyle interventions (e.g. include both providing dietary advice and physical exercise advice) in GDM management if data for the effects of dietary advice could be extracted separately.

Types of participants

Pregnant women with GDM.

Diagnostic criteria for GDM based on oral glucose tolerance test (OGTT) results were defined variously by individual trials according to the policies of local health authorities and professional organisations.

We planned to include trials recruiting pregnant women with normal glycaemia, GDM or pre-existing diabetes mellitus if subgroup data for women with GDM could be extracted separately.

Women were eligible regardless of gestation, age, parity or plurality.

Types of interventions

We planned to include any type of dietary advice for women with GDM in the review.

We planned to compare different types of dietary advice with each other. We intended to compare two or more forms of the same type of dietary advice against each other, i.e. standard dietary advice compared with individualised dietary advice, individual dietary education sessions compared with group dietary education sessions. We intended to compare different intensities of dietary intervention with each other, i.e. single dietary counselling session compared with multiple dietary counselling sessions.

Types of outcome measures

Primary outcomes

Fetal/neonatal outcomes

- 1. Fetal, neonatal or perinatal mortality.
- 2. Large-for-gestational age (LGA) (birthweight greater than or equal to 90^{th} percentile for gestational age).
- 3. Macrosomia (birthweight greater than 4000 g or greater than 4500 g as defined by authors).

Maternal outcomes

1. Mode of birth (normal vaginal birth, operative vaginal birth, caesarean section).

Secondary outcomes

Fetal/neonatal outcomes

- 1. Neonatal hypoglycaemia requiring treatment (variously defined by authors of individual trials).
 - 2. Gestational age at birth.
 - 3. Preterm birth (less than 37 weeks' gestation).
 - 4. Birthweight.

- 5. Small-for-gestational age (SGA).
- 6. Shoulder dystocia.
- 7. Bone fracture.
- 8. Nerve palsy.
- 9. Respiratory distress syndrome.
- 10. Use of assisted ventilation.
- 11. Hyperbilirubinaemia requiring treatment.
- 12. Apgar scores (less than seven at five minutes).
- 13. Apgar scores (less than four at five minutes).
- 14. Ponderal index*.
- 15. Skinfold thickness measurements.
- * A measure of leanness of a person calculated as a relationship between mass and height (can provide valid results even for very short and very tall persons).

Childhood outcomes

- 1. Weight.
- 2. Height.
- 3. Body mass index (BMI).
- 4. Fat mass/fat-free mass.
- 5. Skinfold thickness measurements.
- 6. Blood pressure.
- 7. Impaired glucose tolerance (as defined by author(s)).
- 8. Type 1 diabetes.
- 9. Type 2 diabetes.
- 10. Insulin sensitivity (as defined by author(s)).
- 11. Dyslipidaemia or metabolic syndrome.
- 12. Childhood neurodisability.
- 13. Educational achievement.

Adulthood

- 1. Weight.
- 2. Height.
- 3. BMI.
- 4. Fat mass/fat-free mass.
- 5. Skinfold thickness measurements.
- 6. Blood pressure.
- 7. Impaired glucose tolerance (as defined by author(s)).
- 8. Dyslipidaemia or metabolic syndrome.
- 9. Development of type 1 diabetes.
- 10. Development of type 2 diabetes.
- 11. Insulin sensitivity (as defined by author(s)).
- 12. Educational achievement.

Maternal outcomes

Perinatal

1. Pre-eclampsia.

- 2. Insulin or oral hypoglycaemic agent required for hyperglycaemia.
- 3. Weight gain during pregnancy (according to IOM 2009 pregnancy weight gain guidelines).
 - 4. Induction of labour.
 - 5. Augmentation of labour.
 - 6. Perineal trauma.
 - 7. Postpartum haemorrhage.
- 8. Postpartum infection.
- 9. Adherence to dietary advice.
- 10. Women's sense of well-being and quality of life (as defined by author(s)).
- 11. Women's view of dietary intervention.

Long term

- 1. Postnatal weight retention.
- 2. BMI.
- 3. Gestational diabetes in subsequent pregnancy.
- 4. Development of type 2 diabetes mellitus.
- 5. Development of type 1 diabetes mellitus.
- 6. Impaired glucose tolerance (as defined by author(s)).
- 7. Insulin sensitivity (as defined by author(s)).

Health services cost

- 1. Number of hospital visits/antenatal visits for mother.
- 2. Dietitian visits.
- 3. Medical physician visits.
- 4. Costs to families in relation to the dietary advice provided.
- 5. Length of postnatal stay (mother).
- 6. Cost of maternal care.
- 7. Admission to neonatal nursery/neonatal intensive care unit.
- 8. Length of postnatal stay (baby).
- 9. Cost of offspring care.

Search methods for identification of studies

Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (17 May 2012).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

- 1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
 - 2. weekly searches of MEDLINE;
 - 3. weekly searches of EMBASE;

- 4. handsearches of 30 journals and the proceedings of major conferences:
- 5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and EMBASE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

In addition, we searched the Women and Babies Health and Wellbeing: Action through Trials (WOMBAT) Perinatal Trials Registry (last searched 17 April 2012) using the search terms detailed in Appendix 1.

We did not apply any language restrictions.

Data collection and analysis

Selection of studies

Two review authors independently assessed for inclusion all the potential studies we identified as a result of the search strategy. Disagreements were resolved through discussion and a third review author was consulted. We resolved disagreements through discussion and consulted a third review author as necessary.

Data extraction and management

We designed a form to extract data. For eligible studies, at least two review authors extracted the data using the agreed form. We resolved discrepancies through discussion. We entered data into Review Manager software (RevMan 2011) and checked for accuracy.

When information regarding any of the above was unclear, we attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved any disagreement by discussion or by involving a third assessor.

(1) Sequence generation (checking for possible selection bias)

We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
 - unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal the allocation sequence and determine whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or nonopaque envelopes, alternation; date of birth);
 - · unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding would be unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes. We assessed the methods as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel.

(3.2) Blinding of outcome assessment (checking for possible detection bias)

We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed methods used to blind outcome assessment as:

· low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we re-included missing data in the analyses which we undertook.

We assessed methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
 - unclear risk of bias.

(5) Selective bias (checking for reporting bias)

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We assessed the methods as:

- low risk of bias (where it was clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review had been reported);
- high risk of bias (where not all the study's pre-specified outcomes had been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest were reported incompletely and so could not be used; study fails to include results of a key outcome that would have been expected to have been reported);
 - unclear risk of bias.

(6) Other sources of bias

We described for each included study any important concerns we had about other possible sources of bias.

We assessed whether each study was free of other problems that could put it at risk of bias:

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. We planned

to explore the impact of the level of bias through undertaking sensitivity analyses - see Sensitivity analysis.

Measures of treatment effect

Dichotomous data

For dichotomous data, we presented results as risk ratio with 95% confidence intervals.

Continuous data

For continuous data, we used the mean difference and 95% confidence intervals if outcomes were measured in the same way between trials. We used the standardised mean difference to combine trials that measured the same outcome, but used different methods.

Unit of analysis issues

Cluster-randomised trials

We did not identify any cluster-randomised trials for inclusion. However, if we identify cluster-randomised trial in future updates of this review, we will include them in the analyses along with individually-randomised trials. We will adjust their sample sizes using the methods described in the Handbook using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely. We will also acknowledge heterogeneity in the randomisation unit

We will also acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

Dealing with missing data

For included studies, we noted levels of attrition. If we had identified studies with high levels of missing data, we would have used sensitivity analysis to explored the impact of including studies with high levels of missing data in the overall assessment of treatment effect.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses, and all participants were analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the T^2 , I^2 and Chi^2 statistics. We regarded heterogeneity as substantial if the I^2 was greater than 30% and either the T^2 was greater than zero, or there was a low P value (less than 0.10) in the Chi² test for heterogeneity.

Assessment of reporting biases

In future updates of this review, if there are 10 or more studies in the meta-analysis we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually. If we detect asymmetry, we will perform exploratory analyses to investigate it.

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2011). We used fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e. where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected, we planned to use random-effects meta-analysis to produce an overall summary if an average treatment effect across trials was considered clinically meaningful. The randomeffects summary would have been treated as the average range of possible treatment effects and we would have discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we did not combine trials.

When we used random-effects analyses, we have presented the results as the average treatment effect with its 95% confidence interval, and the estimates of T^2 and I^2 .

Subgroup analysis and investigation of heterogeneity

If we had identified substantial heterogeneity, we would have investigated it using subgroup analyses and sensitivity analyses. We planned to consider whether an overall summary was meaningful, and if it was, use random-effects analysis to produce it.

Maternal characteristics, ways of delivering dietary advice and intensities of the dietary intervention might have significant effects on pregnancy outcomes. We planned to carry out the following subgroup analyses, however, there were insufficient data to do so.

1. Maternal characteristics

- Maternal age:
- greater than or equal to 35 years of age will be compared with below 35 years of age.
 - Ethnicity:
- o ethnic groups of Hispanic, African-American, Asian-American, native American, African, Asian and Pacific islanders and indigenous Australian compared with white ethnicity.
 - Parity:
 - o parity of 0 compared with 1-2;
 - o parity of 0 compared with 3 or more.
 - Maternal education level:
 - o less than 12 years compared with 12 years or more.
 - Maternal body mass index (BMI) at or before trial entry:
- $\,\circ\,$ BMI ranges of 18.5 to 24.9 kg/m² compared with less than 18.5 kg/m²;
- $\circ~BMI$ ranges of 18.5 to 24.9 kg/m² compared with 25 to 29.9 kg/m²;
- $\circ~$ BMI ranges of 18.5 to 24.9 kg/m² compared with 30 kg/m² to 39.9 kg/m²;
- $\,\circ\,$ BMI ranges of 18.5 to 24.9 kg/m² compared with 40 kg/m² or more.

2. Ways of delivering dietary advice

- Standard dietary advice compared with individualised dietary advice.
- Individual dietary counselling session compared with group dietary education session.
- Face-to-face dietary intervention compared with non-face-to-face dietary intervention (e.g. phone counselling, information package, etc.).

3. Intensities of dietary intervention

• Single dietary counselling session compared with multiple dietary counselling sessions.

We planned to use primary outcomes in subgroup analyses. We planned to assess differences between subgroups by interaction tests where possible.

Sensitivity analysis

We did not conduct any sensitivity analysis in this review. In future updates, we plan to carry out sensitivity analysis to explore the effects of trial quality assessed by allocation concealment and other risk of bias components, by omitting studies rated as inadequate for these components. Sensitivity analysis will be restricted to the primary outcomes.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

Results of the search

We identified a total of 16 trials. Fifteen trials were identified through the search conducted by the Cochrane Pregnancy and Childbirth Group and one additional trial was identified through the search of the WOMBAT (**Wom**en and **B**abies health and well-being: **A**ction through **T**rials) perinatal trial registry (WOMBAT 2011) by review authors. Following the application of eligibility criteria, we included nine trials (Balas-Nakash 2010; Cypryk 2007; Grant 2011; Lauszus 2001; Louie 2011; Magee 1990; Moses 2009; Rae 2000; Reece 1995) and excluded seven trials (Gillen 2004; Gillmer 1986; Ilic 1999; Knopp 1991; Ma 2011; Nolan 1984; Reader 2006). *See* Characteristics of included studies and Characteristics of excluded studies.

Included studies

Of the nine included trials, three were conducted in Australia (Louie 2011; Moses 2009; Rae 2000), two were conducted in the United States (Magee 1990; Reece 1995); one trial each was from Canada (Grant 2011), Denmark (Lauszus 2001), Mexico (Balas-Nakash 2010) and Poland (Cypryk 2007).

Participants

A total of 437 women and 444 babies were recruited to the nine trials, with outcome data available for 429 women and 436 babies.

Maternal trial entry weight and BMI

In Louie 2011, 68% of 92 study participants had a pre-pregnancy body mass index (BMI) of less than 25 kg/m²; the pre-pregnancy mean BMI [SD] was 23.9 [4.4] kg/m² for women in the low-GI group and 24.1 [5.7] kg/m² for those in the high-fibre moderate glycaemic index (GI) diet group. In Moses 2009, the mean trial entry BMI [SD] was 32.0 [1.2] kg/m² for the 31 women in the low-GI diet group and 32.8 [1.4] kg/m² for the 32 women in the high-GI diet group. Magee 1990 recruited 12 women who were obese at trial entry; obesity in this trial was defined as greater than 120% of their ideal body weight (according to the corrected 1959 Metropolitan Life Insurance tables) (Magee 1990). Rae 2000 included 117 women whose respective weights were greater than 110% of their ideal weight (100% ideal body weight was defined as BMI of 25 kg/m²).

Three trials did not report trial entry weight for the subgroup of women with GDM in their studies (Balas-Nakash 2010; Grant 2011; Reece 1995). Women with both GDM and T2DM were included in Balas-Nakash 2010; women with GDM and insulindependent diabetes were included in Reece 1995 and women with GDM and impaired glucose tolerance without meeting GDM diagnostic criteria were included in Grant 2011.

In Lauszus 2001, women were recruited after their diagnosis of GDM and were then instructed to follow a high-carbohydrate diet until the 34th week of pregnancy where women were randomised into two groups. No information was reported on women's weight and BMI at recruitment, but a baseline weight was reported for women at randomisation (33 weeks of gestation) (Lauszus 2001). The mean BMI [SD] at 33 weeks' gestation were 35 [2.4] kg/m² and 32.2 [1.5] kg/m² for women in the high-monounsaturated fatty acids diet group and the high-carbohydrate diet group, respectively (Lauszus 2001),

No data were reported for women's BMI at trial entry in Cypryk 2007.

Diagnosis of GDM

Different GDM diagnostic criteria were used in the nine included trials. The Australian Diabetes in Pregnancy Society (ADIPS) criteria were used in two trials (Louie 2011; Moses 2009). One trial each used the American Diabetes Association (ADA) criteria (Magee 1990), Canadian Diabetes Association (CDA) criteria (Grant 2011) and World Health Organization (WHO) criteria (Cypryk 2007). Lauszus 2001 used three-hour 75 grams oral glucose tolerance test (OGTT) for GDM diagnosis, and GDM was defined as two or more plasma glucose samples above three standard deviations of the mean. Rae 2000 used criteria as fasting blood glucose level (BGL) greater than 5.4 mmol/L and/or two-hour BGL greater than 7.9 mmol/L in 75 grams OGTT.

There is no information on GDM diagnostic criteria in Balas-Nakash 2010 and Reece 1995.

See Characteristics of included studies for details.

Intervention and comparison

Four trials assessed the effect of a low-GI food or diet in GDM management (Balas-Nakash 2010; Grant 2011; Louie 2011; Moses 2009). In Balas-Nakash 2010, women in the low-GI diet group were advised to select low-to-moderate GI carbohydrate food, while women in the control group were allowed any type of carbohydrate food. There was no information reported on the definitions for low-GI carbohydrate, moderate-GI carbohydrate or high-GI carbohydrate in this study (Balas-Nakash 2010). Grant 2011 advised women in the low-GI diet group to select their starch food from an exchange list of low- and intermediate- GI choices, while women in the comparison group were asked to select their starch choices from an exchange list of intermediate- and high-

GI food (Grant 2011). Food exchange lists for study diets were provided in the published report for Grant 2011, which indicated that the carbohydrate food recommended for women in low-GI diet group having a GI range of 26-66 and for women in the control group having a GI range of 58 to 87. In Moses 2009, women in the low-GI diet group were advised to select low-GI food (55 or less) based on the international tables of GI and glycaemic load values (Atkinson 2008) and women in the comparison group were advised to follow a high-fibre, low-sugar diet, with no specific mention of the GI.

In Louie 2011, a low-GI diet aiming for a GI target of no higher than 50, was compared with a moderate-GI diet (GI around 60). Two trials compared an energy-restricted diet with a no energy restriction diet (Magee 1990; Rae 2000). Women in Magee 1990 were hospitalised during the intervention period. In the first week of hospitalisation, women in both groups had a 2400 kcal/day diet, with 50% total energy derived from carbohydrate, 30% from fat and 20% from protein (Magee 1990). During the second week of hospitalisation, one group of women continued the diet consumed in the first week, while women in the other group restricted their daily energy intake to 1200 kcal, which was achieved by reducing serving size without changing diet content (Magee 1990). In Rae 2000, a 6800 kJ to 7600 kJ per day diet was compared with a diet providing 8600 kJ to 9500 kJ energy.

Two trials focused on specific nutrients in the diet (Lauszus 2001; Reece 1995). Lauszus 2001 compared a high-carbohydrate diet with a high-monounsaturated fat diet, without specifying the proportion of daily energy sources for a high carbohydrate or a high monounsaturated fat. In Reece 1995, a diet containing 80 grams of fibre per day was compared with a standard ADA diet providing 20 grams fibre per day.

One trial assessed different proportions of energy derived from carbohydrate, protein and fat (Cypryk 2007). Women in the low-carbohydrate group had 45% of their daily energy from carbohydrate, 25% from protein and 30% from fat; women in the high-carbohydrate group derived 60% daily energy from carbohydrate, 25% from protein and 15% from fat (Cypryk 2007).

Therefore, we structured the comparisons as:

- Low-moderate GI food versus moderate-high GI food: Balas-Nakash 2010; Grant 2011; Moses 2009;
- Low-GI diet versus high-fibre moderate-GI: Louie 2011;
- Energy-restricted diet versus no energy restriction diet: Magee 1990; Rae 2000;
- Low-carbohydrate diet versus high-carbohydrate diet: Cypryk 2007.
- High-monounsaturated fat diet versus high-carbohydrate diet: Lauszus 2001;
- Standard-fibre (20 grams fibre/day) diet versus high-fibre (80 grams fibre/day) diet: Reece 1995.

See Characteristics of included studies for further details.

Outcome

Seven included studies focused on perinatal outcomes for women and their babies without any longer-term outcomes reported (Balas-Nakash 2010; Cypryk 2007; Grant 2011; Louie 2011; Moses 2009; Rae 2000; Reece 1995). One trial reported maternal and infant perinatal outcomes as well as maternal early postnatal outcomes of postnatal BMI and development of glucose intolerance or type 2 diabetes (up to nine months postpartum) (Lauszus 2001). One trial reported biochemical outcomes only (Magee 1990).

See Characteristics of included studies for more details.

Excluded studies

A total of six trials were excluded. We excluded three trials as they compared different types of care for women with GDM, where dietary advice was included as part of the care (Gillen 2004; Gillmer 1986; Reader 2006). Another two trials were excluded as they were cross-over studies (Ilic 1999; Nolan 1984). Knopp 1991 was excluded as it was a systematic review, not a clinical trial. See Characteristics of excluded studies for further details.

Risk of bias in included studies

The nine included studies had various levels of risk of bias. *See* Figure 1 and Figure 2 for details.

Figure 1. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

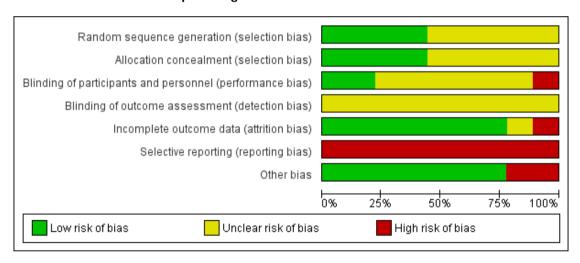
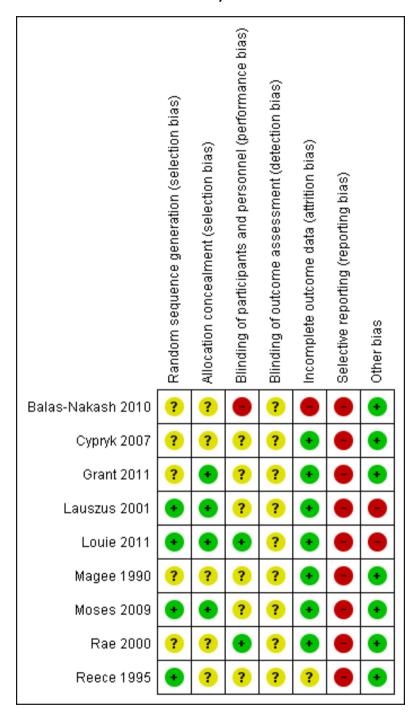


Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.



Allocation

Four of the nine trials were at low risk of bias for sequence generation (Lauszus 2001; Louie 2011; Moses 2009; Reece 1995) with the remainder of trials unclear or not reporting this component. Four trials reported adequate allocation concealment methods (Grant 2011; Lauszus 2001; Louie 2011; Moses 2009) with the remainder not reporting their method or not reporting it clearly. In Grant 2011, numbered, sealed, opaque envelopes were used and the randomisation order was generated by one of the investigators who was not involved in recruitment. Randomisation in Lauszus 2001 was performed by a third person at an independent centre. In Louie 2011, women were centrally randomised to study groups by computer-generated random numbers and the recruiter was not able to predict the allocation sequence. In Moses 2009, the allocation method was not reported in detail but was judged as likely to have been adequately concealed (women were allocated to the study groups using permuted blocks of unequal size with the list generated using STATA).

Blinding

In six trials women were not blinded (Balas-Nakash 2010; Cypryk 2007; Grant 2011; Lauszus 2001; Moses 2009; Reece 1995). Two trials reported that participants were blinded to group allocation (Louie 2011; Rae 2000). One trial did not provide information on whether or not the participants were blinded (Magee 1990). Eight trials did not report whether the outcome assessors were blinded to group allocation (Balas-Nakash 2010; Cypryk 2007; Grant 2011; Lauszus 2001; Magee 1990; Moses 2009; Rae 2000; Reece 1995). One trial reported that the unblinded research dietitian was involved in outcome data collection (Louie 2011).

Incomplete outcome data

Seven included trials were judged as being at low risk for attrition bias (Cypryk 2007; Grant 2011; Lauszus 2001; Louie 2011; Magee 1990; Moses 2009; Rae 2000). One trial was rated as high risk of attrition bias (Balas-Nakash 2010) and another having an unclear risk of attrition bias (Reece 1995).

Three trials reported no losses to follow-up or post randomisation exclusions (Cypryk 2007; Magee 1990; Moses 2009). In Lauszus 2001, Louie 2011 and Rae 2000, small numbers of women were lost to follow up or withdrew after randomisation with reasons reported and were unlikely to affect the results. In Grant 2011, three (10.3%) women in the low-GI group withdrew after randomisation, reasons were given and data analyses were based on an intent-to-treat basis.

In Balas-Nakash 2010, of a total of 108 women potentially eligible women who were involved in another clinical trial, 20 declined

(15.8%) with no reason reported and another 19 women (17.5%) were excluded due to incomplete dietary information. No information was available on the characteristics of these declined and excluded women (Balas-Nakash 2010). With the remaining 69 women in Balas-Nakash 2010, 37 were diagnosed with GDM and provided outcome data in this review. In Reece 1995, 61 women with insulin-dependent diabetes or GDM were included, 11/61 (18%) women were excluded after randomisation without specifying the numbers of women with insulin-dependent diabetes and GDM. Reasons for exclusion were reported as: spontaneous abortion (one women), moved away (two women), and noncompliant (four women in each of the study groups) (Reece 1995).

Selective reporting

All nine included trials were at high risk of reporting bias (Balas-Nakash 2010; Cypryk 2007; Grant 2011; Lauszus 2001; Louie 2011; Magee 1990; Moses 2009; Rae 2000; Reece 1995). Most of the prespecified health outcomes for women and their babies were not reported in included trials (Balas-Nakash 2010; Cypryk 2007; Grant 2011; Lauszus 2001; Louie 2011; Moses 2009; Rae 2000; Reece 1995). One trial only reported biochemical outcomes without any information provided on the health outcomes for women and their babies (Magee 1990).

Other potential sources of bias

There was no obvious risk of other potential sources of bias in seven trials (Balas-Nakash 2010; Cypryk 2007; Grant 2011; Magee 1990; Moses 2009; Rae 2000; Reece 1995).

In Lauszus 2001, women in the high-monounsaturated fat diet group had a higher trial entry BMI (mean [SD]: 35 [2.4] kg/m²) when compared with women in the high-carbohydrate group (mean [SD]: 32.2 [1.5] kg/m²). In Louie 2011, baseline blood glucose concentrations at two hours post 75 grams glucose load were significantly different between the study groups (mean [SD]: 8.6 [1.2] mmol/L for women in the low-GI group, 8.0 [1.3] mmol/L for women in the high-fibre group, P = 0.024).

Effects of interventions

Eleven different types of dietary advice for women with GDM were assessed under six different comparisons (see Data and analyses).

Primary outcomes

Low-moderate GI food versus moderate-high GI food

Three trials involving 126 women and their babies contributed data to this comparison (Balas-Nakash 2010; Grant 2011; Moses 2009). Authors from Grant 2011 and Moses 2009 provided additional unpublished outcome data.

Fetal or neonatal mortality was not reported in any of these trials (Balas-Nakash 2010; Grant 2011; Moses 2009). No significant differences were seen in the rates of macrosomia (two trials, 89 infants, risk ratio (RR) 0.45, 95% confidence interval (CI) 0.10 to 2.08) (Analysis 1.1) and large-for-gestational age (LGA) (two trials, 89 infants, RR 0.95, 95% CI 0.27 to 3.36) between the two study groups (Analysis 1.2). No significant differences were seen in the rates of caesarean section (one trial, 63 women, RR 0.66, 95% CI 0.29 to 1.47) (Analysis 1.3), operative vaginal birth (one trial, 63 women, RR 0.62, 95% CI 0.16 to 2.37) (Analysis 1.4) and normal vaginal birth (one trial, 63 women, RR 1.35, 95% CI 0.89 to 2.07) (Analysis 1.5) between women in the two study groups.

Low-GI diet versus high-fibre moderate-GI diet

One trial (Louie 2011) involving 92 women and their babies contributed data for this comparison. Authors were contacted for full report before the publication of this trial (Louie 2011).

No information was provided on fetal or neonatal mortality. No significant differences were seen in the rates of macrosomia (birthweight greater than 4000 g) (one trial, 92 infants, RR 0.32, 95% CI 0.03 to 2.96) (Analysis 2.1) and LGA (one trial, 92 infants, RR 2.87, 95% CI 0.61 to 13.50) (Analysis 2.2) between babies born to women in the low-GI diet group and high-fibre moderate-GI diet group. No significant difference in caesarean section rate was seen between women in the two study groups (one trial, 88 women, RR 1.80, 95% CI 0.66 to 4.94) (Analysis 2.3).

No data reported on operative vaginal birth or normal birth.

Energy-restricted diet versus no energy restriction diet

Two trials (Rae 2000 (117 women and 124 babies); Magee 1990 (12 women and their babies)) assessed the effects of energy-restricted diet for women with GDM. Magee 1990 did not report any birth outcome data.

There were no fetal deaths reported (one trial, 124 infants) (Analysis 3.1) and neonatal mortality was not reported (Rae 2000). Macrosomia was defined as birthweight at least 4000 grams or at least 90th centile weight for gender, gestational age and maternal height classified according to the Peinatal Statistics in Western Australia for macrosomia in Rae 2000. No significant differences were seen in the rates of macrosomia (one trial, 122 infants, RR 1.56, 95% CI 0.61 to 3.94) (Analysis 3.2) and LGA (one trial, 123 infants, RR 1.17, 95% CI 0.65 to 2.12) (Analysis 3.3) between babies born to women in the energy-restricted diet and no energy restriction diet.

For maternal primary outcomes, there were no significant differences seen for the rates of caesarean section (one trial, 121 infants,

RR 1.18, 95% CI 0.74 to 1.89) (Analysis 3.4), operative vaginal birth (one trial, 121 infants, RR 0.98, 95% CI 0.38 to 2.54) (Analysis 3.5) and normal vaginal birth (one trial, 121 infants, RR 0.89, 95% CI 0.63 to 1.27) (Analysis 3.6) between the two study groups.

Low-carbohydrate diet (\leq 45% daily total energy intake from carbohydrate) versus high-carbohydrate diet (\geq 50% daily total energy intake from carbohydrate)

One trial (Cypryk 2007) involving 30 women and their babies contributed data for this comparison.

No data were reported on fetal or neonatal mortality. None of the infants were macrosomic (Analysis 4.1). There were no significant differences between the two study groups in the rates of caesarean section (one trial, 30 women, RR 1.40, 95% CI 0.57 to 3.43) (Analysis 4.2), operative vaginal birth (one trial, 30 women, RR 1.00, 95% CI 0.07 to 14.55) (Analysis 4.3) and normal vaginal birth (one trial, 30 women, RR 0.78, 95% CI 0.39 to 1.54) (Analysis 4.4).

High-monounsaturated fat diet (at least 20% total energy from monounsaturated fat) versus high-carbohydrate diet (at least 50% total energy from carbohydrate)

One trial (Lauszus 2001) involving 27 women and their babies contributed data for this comparison. The author was contacted and contributed additional unpublished outcome data.

No information was provided on fetal or neonatal mortality. No significant differences were seen in the rates of macrosomia (birthweight greater than 4000 grams) (one trial, 27 infants, RR 0.65, 95% CI 0.19 to 2.18) (Analysis 5.1) and LGA (one trial, 27 infants, RR 0.54, 95% CI 0.21 to 1.37) (Analysis 5.2) between babies born to women in the high-monounsaturated fat diet group and to women in the high-carbohydrate diet group.

No data on maternal primary outcomes was reported.

Standard-fibre (20 grams fibre/day) diet versus high-fibre (80 grams fibre/day) diet

One trial involving 22 women with GDM and their babies contributed data to this comparison (Reece 1995).

No data were available on maternal and child primary outcomes under this comparison.

Secondary outcomes

Low-moderate GI food versus moderate-high GI food

No significant differences were seen between the two study groups for the outcomes of birthweight, gestational age at birth, smallfor-gestational age (SGA), induction of labour and preterm birth (Analysis 1.6; Analysis 1.7; Analysis 1.8; Analysis 1.9; Analysis 1.10). A random-effects analysis was used for the outcome of insulin or oral hypoglycaemic agent required for hyperglycaemia as significant heterogeneity was noted ($Tau^2 = 0.41$; $I^2 = 78\%$). This may due to the different criteria used in different trials for hypoglycaemic agents (Balas-Nakash 2010; Grant 2011; Moses 2009). On average, there was no significant difference in the use of insulin or hypoglycaemic agent between women in the two study groups, but the treatment effects of two trials were strongly in opposite directions, so it is possible that both positive and negative effects will be found in different trials and populations (Analysis 1.11). In Balas-Nakash 2010, women's adherence to dietary advice was assessed by three different methods including adaption of calorie intake, adherence questionnaire and self-perception of adherence. There were no subset data reported on the adherence to dietary advice for women with GDM (Balas-Nakash 2010). Grant 2011 reported all participants in the low-GI group rated the foods as being "good" and indicated they would consider continuing these low-GI foods postpartum; no separate data were reported on adherence to diet advice for the women with GDM. No information was reported on women's adherence to dietary advice in Moses 2009.

There were no data reported on other prespecified secondary review outcomes.

Low-GI diet versus high-fibre moderate-GI diet

There were no significant differences in birthweight (one trial, 92 infants, mean difference (MD) 0.00 g, 95% CI -277.18 to 277.18) (Analysis 2.4). Gestational age at birth (one trial, 92 infants, MD -0.10 weeks, 95% CI -0.39 to 0.19) (Analysis 2.5); preterm birth (one trial, 92 infants, RR 0.96, 95% CI 0.14 to 6.51) (Analysis 2.6) and SGA (one trial, 92 infants, RR 1.20, 95% CI 0.34 to 4.18) (Analysis 2.7) showed no differences between groups. No significant differences were seen in the ponderal index for infants born to women in the two study groups (one trial, 92 infants, MD 0.20 kg/m³, 95% CI -0.79 to 1.19) (Analysis 2.8).

Gestational weight gain for women in the low-GI diet group was not significantly different when compared with the high-fibre moderate-GI diet group (one trial, 87 women, MD -1.20 kg, 95% CI -3.43 to 1.03) (Analysis 2.9). There was no significant difference seen in the number of women required insulin treatment for hyperglycaemia between the two study groups (one trial, 92 women, RR 0.83, 95% CI 0.58 to 1.17) (Analysis 2.11). Adherence to dietary intervention was assessed by a 24-hour recall when women were attending their dietitian appointments (Louie 2011); there was no significant difference seen in the number of women who were adherent to the study diets (one trial, 92 women, RR 0.84, 95 %CI 0.64 to 1.11) (Analysis 2.10).

There were no data available on other prespecified secondary review outcomes.

Energy-restricted diet versus no energy restriction diet

There were no significant differences in the outcomes of induction of labour (one trial, 114 women, RR 1.02, 95% CI 0.68 to 1.53) (Analysis 3.7), pre-eclampsia (one trial, 117 women, RR 1.00, 95% CI 0.51 to 1.97) (Analysis 3.8) and insulin required for maternal hyperglycaemia (one trial, 117 women, RR 1.05, 95% CI 0.47 to 2.34) (Analysis 3.9). Fasting plasma glucose and fasting plasma insulin were reported in a single, small randomised trial involving 12 women; no significant differences were see in fasting plasma glucose (standardised mean difference (SMD -0.35 mmol, 95% CI -1.51 to 0.81) and fasting plasma insulin (SMD -0.17 pM, 95% CI -1.32 to 0.98) between the two study groups (Analysis 3.10). Outcomes including shoulder dystocia, birthweight, gestational age at birth were reported in one trial (Rae 2000) but since numbers in each group were unclear or these outcomes, no data were able to be included in the review.

Adherence to dietary intervention in Rae 2000 was assessed by three-day food diaries. Women in the energy-restricted diabetic diet group consumed slightly less (97%) energy than the diet goal of 6800 kJ/day to 7600 kJ/day; whereas women in the no energy restriction diabetic diet consumed considerably less energy (77%) than the dietary goal of 8600 Kj/day to 9500 Kj/day. As a result, there was no significant difference between average daily energy intake between women in the two groups (Rae 2000).

No data were reported on other secondary review outcomes.

Low-carbohydrate diet (\leq 45% daily total energy intake from carbohydrate) versus high-carbohydrate diet (at least 50% daily total energy intake from carbohydrate)

There were no significant differences seen in birthweight (one trial, 30 infants, MD 22.00 g, 95% CI -241.06 to 285.06) (Analysis 4.5) or gestational age at birth (one trial, 30 infants, MD 0.10 week, 95% CI -0.83 to 1.03) (Analysis 4.6) between the two study groups. Adherence to dietary advice was reported as 12/15 (80%) in the low-carbohydrate group and 11/15 (73.3%) in the high-carbohydrate diet group (full adherence to recommended menu) (Cypryk 2007). Twenty (66.7%) women reported no symptoms of hunger, seven women reported hunger after breakfast on the first few days of the study period and three women reported most intense hunger before breakfast (Cypryk 2007). None of the women experienced any symptoms of intolerance towards the recommended diets (Cypryk 2007).

There were no data reported on other prespecified secondary review outcomes.

High-monounsaturated fat diet (at least 20% total energy from monounsaturated fat) versus high-carbohydrate diet (at least 50% total energy from carbohydrate)

There were no significant differences in birthweight (one trial, 27 infants, MD 1.00 g, 95% CI -112.85 to 114.85) (Analysis 5.3)

and gestational age at birth (one trial, 27 infants, MD 0.10 week, 95% CI -0.13 to 0.33) (Analysis 5.4).

None of the women developed pre-eclampsia (Analysis 5.5) or needed insulin for hyperglycaemia (Analysis 5.6) (Lauszus 2001). Women in the high-monounsaturated fat diet group were significantly heavier in late pregnancy (third trimester) (Analysis 5.7) and had a significantly higher BMI during late pregnancy (third trimester) (Analysis 5.8) and at six to nine months postpartum (one trial, 27 women, MD 4.10 kg/m², 95% CI 2.34 to 5.86) (Analysis 5.9), when compared with women in the high-carbohydrate diet group. However, it is important to note a significant BMI difference existed at trial entry between women in the two study groups, and in the original analysis carried out by the authors was adjusted for BMI (Lauszus 2001). There were no significant differences seen in the incidence of developing type 2 diabetes within six weeks postpartum (one trial, 24 women, RR 2.00, 95% CI 0.45 to 8.94) (Analysis 5.10) and four months or more postpartum (one trial, six women, RR 1.00, 95% CI 0.10 to 9.61) (Analysis 5.10) between women in the two study groups. No significant differences were seen in the incidence of developing glucose intolerance without meeting type 2 diabetes diagnostic criteria within six weeks postpartum (one trial, 24 women, RR 1.50, 95% CI 0.30 to 7.43) (Analysis 5.11) and four months or more postpartum (one trial, seven women, RR 0.27, 95% CI 0.01 to 4.93) (Analysis 5.11). Insulin sensitivity was assessed by using an intravenous glucose tolerance test (Galvin 1992), with no significant difference seen in maternal fasting glucose, fasting insulin and insulin sensitivity during pregnancy between the two study

There were no data available on other prespecified secondary review outcomes.

Standard-fibre (20 grams fibre/day) diet versus high-fibre (80 grams fibre/day) diet

When compared with infants born to women having a standard ADA diet (with 20 grams fibre per day), there were no significant difference seen in birthweight (one trial, 22 infants, MD -94.00 g, 95% CI -446.71 to 258.71) (Analysis 6.1) and gestational age at birth (one trial, 22 infants, MD 0.00 week, 95% CI -1.30 to 1.30) (Analysis 6.2). No women required insulin treatment for hyperglycaemia during pregnancy (Reece 1995) (Analysis 6.3). No significant difference was seen in gestational weight gain between women in the two study groups (one trial, 22 women, MD 2.40 kg, 95% CI -2.20 to 7.00) (Analysis 6.4). No information was given on the start and end point weights used for calculating weight change in the trial provided outcome data (Reece 1995).

Women were instructed to keep daily food records for assessing their compliance to the study dietary intervention (Reece 1995). Dietary compliance was rated as good in 60% and acceptable in 40% of the whole sample size, which included both women with type 2 diabetes and GDM (Reece 1995). No subset data were

reported on the adherence to dietary advice for women with GDM (Reece 1995).

No data were available on other prespecified secondary review outcomes.

Subgroup analyses and sensitivity analyses

Due to the small number of studies included and limited data available, no subgroup analyses and sensitivity analyses were conducted.

DISCUSSION

Summary of main results

Diet comparisons including low-moderate GI food versus high-moderate GI food; low-GI diet versus high-fibre moderate-GI diet; energy-restricted diet versus no energy restriction diet; low-carbohydrate diet versus high-carbohydrate diet; high-monounsaturated fat diet versus high-carbohydrate diet; standard-fibre diet providing 20 grams fibre per day versus fibre-enriched diet providing 80 grams fibre per day were investigated in this review. No significant differences were seen in any of the reported primary outcomes. Based on the current very limited data, it remains unclear which diet is the most suitable diet for women with GDM in improving the health for women and their babies in the short or long term.

Overall completeness and applicability of evidence

The evidence on different dietary advice for women with GDM is incomplete. Although a wide range of dietary advice was investigated, very limited outcome data were reported for each of the dietary comparisons and most reported outcomes were based on data from individual studies.

In the comparison of standard ADA diet (20 grams fibre/day) versus fibre-enriched diet (80 grams fibre/day), none of the review's primary outcomes were reported (Reece 1995). One trial reported biochemical outcomes only, without any information provided on clinical outcomes for the women and their babies under the comparison of energy-restricted diet versus no energy restriction diet (Magee 1990). For longer term outcomes, only very limited data from one small randomised trial were available on postpartum BMI, future development of type 2 diabetes and future development of glucose intolerance without meeting type 2 diabetes diagnostic criteria (Lauszus 2001). No data were available on any other maternal or child longer term outcomes and health service cost.

Due to the small number of studies involved in each of the dietary comparisons, various levels of risk of bias of the included studies and small numbers of participants, the applicability of the current available evidence was very limited.

Quality of the evidence

A total of nine small trials were included (437 women, 444 babies); outcome data were available from 429 women and 436 babies . The majority of the comparisons in this review were based on data from one or two small trials. The quality of the evidence for each of the dietary comparisons greatly depends on the quality of the one or two trial(s) which provided outcome data.

Risk of bias varied across the nine included trials in this review. Four included studies (Grant 2011; Lauszus 2001; Moses 2009; Rae 2000) had low-to-moderate risk of bias. Three included trials (Cypryk 2007; Louie 2011; Reece 1995) were of moderate-to-high risk of bias. Published reports for Balas-Nakash 2010 and Magee 1990 did not allow a detailed assessment of their risk of bias. Due to the nature of behavioural interventions, blinding of participants was not implemented in six out of the nine trials (Balas-Nakash 2010; Cypryk 2007; Grant 2011; Lauszus 2001; Moses 2009; Reece 1995). Blinding of outcome assessor(s) was unclear in all nine included trials (Balas-Nakash 2010; Cypryk 2007; Grant 2011; Lauszus 2001; Louie 2011 Magee 1990; Moses 2009; Moses 2009; Rae 2000; Reece 1995).

Women's adherence to dietary interventions may have had an impact on outcomes of interventions, with some suggested dietary changes easier to adopt than others. Furthermore, in Rae 2000, there was no significant difference between average daily energy intake between women in the energy-restricted diabetic diet group and group with no energy restriction, which may have contributed to the research findings of no significant difference on pregnancy outcomes between women in the two groups. In Lauszus 2001, authors referred to study groups as high-carbohydrate diet group and high-monounsaturated fatty acids diet without giving a clear definition about this in terms of foods, making it hard to judge women's adherence. In Balas-Nakash 2010, Grant 2011 and Reece 1995, a mixed population including women with type 2 diabetes and women with GDM were included. None of the three trials reported dietary adherence for the subgroup of women with GDM; or the GI values of their actual food intake (Balas-Nakash 2010; Grant 2011; Reece 1995).

The remaining four trials did not report information about women's adherence to dietary interventions (Cypryk 2007; Louie 2011; Magee 1990; Moses 2009).

Potential biases in the review process

Systematic searches of all potential eligible trials were carried out by the Trials Search Co-ordinator of the Cochrane Pregnancy and Childbirth Group. We also searched the WOMBAT (**Wom**en and **B**abies health and wellbeing: **A**ction through **T**rials) perinatal trial database (WOMBAT 2011) (Last Search: 17 April 2012) and reference list of the identified potential trials. Authors of the included trials were also contacted via email for additional data where possible during the review process.

One potential bias introduced during the review process may be the definition of eligible women for this review. We used the definition of GDM according to the diagnostic criteria selected by trial authors. Due to the inconsistencies existing in GDM diagnostic methods around the world, we may have included women with various degrees of pregnancy hyperglycaemia.

Another possible bias may have been introduced when we grouped trials under different comparisons for data synthesis. For the comparison of low-carbohydrate diet versus high-carbohydrate diet, there was only one trial that provided outcome data (Cypryk 2007). In this trial, women in the low-carbohydrate diet group had a 30% energy from fat while those in the high-carbohydrate diet group had only 15% energy from fat (Cypryk 2007). A 50% difference in diet fat content may have introduced bias to a comparison that focused on carbohydrate only. In addition, in the comparison of energy-restricted diet versus no energy restriction diet, the two trials included under this comparison actually had different levels of energy restrictions; one trial had 50% energy restriction and the other had 20% to 30% energy restriction (Magee 1990; Rae 2000). Combining evidence from two trials with different levels of energy restriction may have introduced bias, although in this current review, only one of the two trials contributed outcome

Agreements and disagreements with other studies or reviews

In this review, we did not find enough evidence to suggest the most suitable diet compositions for women with GDM in improving pregnancy outcomes.

There is a systematic review assessing the effect of low-GI diet for women with GDM (Louie 2010). Only one randomised clinical trial (Moses 2009) involving 63 women, was included in this review (Louie 2010). Louie 2010 found a significantly lower proportion of women in the low-GI group met the criteria to commence insulin than women in the high-GI group and there were no significant differences in any other reported pregnancy outcomes. In our review, three included trials involving 126 women contributed data on the outcome of requirement of insulin for pregnancy hyperglycaemia. One trial was the same trial included in Louie 2010. We did not find a significant difference in the requirement of insulin for pregnancy hyperglycaemia for women in the low-GI group when compared with women in the high-GI group; we also did not find any significant differences in other primary and secondary outcomes under this comparison.

Modest calorie restriction, defined as 1600 to 1800 kcal/day or a 33% energy reduction was reviewed in two review papers (Knopp 1991; Reader 2007). Both review papers reported the benefits of optimising glycaemic control and regulating pregnancy weight gain, without increasing the risk of ketosis by having a modest calorie restriction diet for obese women with GDM (Knopp 1991; Reader 2007). Neither reviews report data on pregnancy outcomes (Knopp 1991; Reader 2007). In our review, two trials investigated the effects of energy restriction for women with GDM (Magee 1990; Rae 2000). Pregnancy outcome data were only available from one of the two trials (Rae 2000), which assessed the effects of diet with 20% to 30% energy restriction for women with GDM. We did not find any significant differences in the reported primary outcomes of fetal mortality, macrosomia, large-for-gestational age and mode of birth or the reported secondary outcomes. However, it is important to note that the actual daily energy intake for women in Rae 2000 was not significantly different between the two study groups.

in maternal BMI. In our review, we did not find any other significant benefits or harms of the diets investigated under the six comparisons.

No conclusive suggestions on the most appropriate diets for women with GDM can be made based on currently available evidence from randomised controlled trials.

Implications for research

Further larger trials with sufficient power to assess the effects of different diets for women with GDM on maternal and infant health outcomes are needed. Participants' adherence to dietary interventions and methods about improving intervention adherence need to be addressed and reported. Multi-faceted dietary interventions (i.e. a dietary intervention targeting total energy, proportion of energy from different macronutrients and glycaemic index) may be worth considering when designing future trials. Outcomes such as longer-term health outcomes for women and their babies, women's quality of life and health service cost should be included.

AUTHORS' CONCLUSIONS

Implications for practice

Overall, results were inconclusive due to the very limited number of trials, participants and data available for each of the six dietary comparisons. Women having a high-monounsaturated fat diet (contributing at least 20% total daily energy intake) are more likely to be heavier during the third trimester and have a higher late pregnancy BMI and postnatal BMI when compared with women having a high-carbohydrate diet (contributing at least 50% total daily energy intake). However, it is important to note that these findings are based on very limited data often from single, small randomised trials with data unadjusted for trial entry imbalance

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As part of the pre-publication editorial process, this review has been commented on by three peers (an editor and two referees who are external to the editorial team), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

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^{*} Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Balas-Nakash 2010

Methods	Randomised controlled trial.	
Participants	N = 37 (a total of 69 women were involved in the study, but only 37 women were diagnosed with GDM and provided outcome data for this review) Women of \leq 30 weeks' gestation, diagnosed with Type A2 GDM (see notes), who were planning to give birth at the NIPerIER and who required medical treatment from the Department of Endocrinology at NIPerIER Exclusion criteria: women with T1DM, Type A1 GDM (see notes), glucose intolerance, multiple pregnancies, kidney or liver disease and hyper or hypothyroidism Setting: Mexico.	
Interventions	Low-to-moderate GI diet group (n = 19): only foods with a low-to-moderate GI were recommended Control group (n = 18): any type of carbohydrate was permitted All women: 1. received medical nutrition therapy from a nutritionist and diabetes educator, which included a complete evaluation of nutritional status, nutritional intervention based on a moderate restriction of calorie (24 kcal/kg) and carbohydrate (40% to 45%) intake; 2. weight, weight gain, glycaemic control and initiation of or any alteration to insulin treatment were evaluated in each consultation; 3. received a glucose meter and a finger prick device; frequent capillary glucose selfmonitoring (6 times a day) as an intense educational component; 4. were informed about the importance of measuring their glucose levels, how to use the glucose meter and about the recording of capillary glucose readings.	
Outcomes	Adherence to dietary intervention, diet intake, weight change, insulin use	
Notes	 No GDM diagnostic criteria reported. Type A1 GDM: abnormal OGTT but normal BGLs during fasting and 2 hours after meals; diet modification is sufficient to control glucose levels. Type A2 GDM: abnormal OGTT compounded by abnormal glucose levels during fasting and/or after meals; additional therapy with insulin or other medications is required. 	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as "women included in this study were randomly divided into two study groups", no further information available
Allocation concealment (selection bias)	Unclear risk	No information was given on allocation concealment.

Balas-Nakash 2010 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	It is not feasible to blind study participants due to the nature of behavioural intervention. No information on whether research personnel were blinded or not
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information about whether outcome assessors were blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	Of the total randomised cohort of 108 eligible women (mixed cohort of women with GDM and T2DM) in a clinical trial, 20 declined (15.8%) to participate in the current trial with reasons unclear. Another 19 women (17.5%) were excluded due to incomplete dietary information. No information was available for these excluded participants
Selective reporting (reporting bias)	High risk	Most of the prespecified review outcomes were not reported in this trial
Other bias	Low risk	No obvious risk of other bias.

Cypryk 2007

Methods	Randomised controlled trial.
Participants	N = 30. Caucasian women with newly diagnosed GDM according to WHO criteria (see notes) Exclusion criteria not reported. Setting: Poland.
Interventions	Low-carbohydrate diet group (n = 15): daily total energy divided as carbohydrate:45%, protein: 25%, fat: 30% (based on daily total energy of 1800 Kcal). Women were encouraged to have the diet until birth High-carbohydrate diet group (n = 15): daily total energy divided as carbohydrate: 60%, protein: 25%, fat: 15% (based on daily total energy of 1800 Kcal). Women were encouraged to have the diet until birth All women: 1. before dietary intervention, BGL were recorded from the patients' diaries 3 to 4 days before study intervention; 2. during the first 14 days after the start of interventions, women were asked to HBGM 4 times a day (fasting and 2 hours after breakfast, lunch and dinner); results were recorded in the HBGM diary; 3. on day 15, compliance to nutritional recommendations was assessed, diary reviewed; 4. urine ketones were checked daily.
Outcomes	Obstetric outcomes, BGL, intervention compliance, side-effects of the diet intervention

Cypryk 2007 (Continued)

Notes	GDM diagnosis based on WHO criteria:		
	• fasting BGL \geq 7.0 mmol/L;		
	 2-hour BGL after 75 g glucose load ≥ 7.8 mmol/L; 		
	• 1 or more value(s) is (are) met or exceeded.		

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as "the patients were randomised into two groups", no further details available
Allocation concealment (selection bias)	Unclear risk	No information was given on allocation concealment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	It was not feasible to blind study participants. No information on whether research personnel were blinded or not
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information about whether outcome assessors were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up or post randomisation exclusion.
Selective reporting (reporting bias)	High risk	Most of the prespecified review outcomes were not reported in this trial
Other bias	Low risk	No obvious risk of other bias.

Grant 2011

Methods	Randomised controlled trial.		
Participants	N = 29 Pregnant women aged at 18 to 45 years, diagnosed with GDM according to CDA criteria, and who had been referred to the Diabetes in Pregnancy Clinic (DIP), St.Michael's Hospital, Canada Exclusion criteria: presence of a multiple pregnancy or an acute or chronic illness affecting carbohydrate metabolism; presence of type 1 or type 2 diabetes prior to the current pregnancy; use of insulin treatment prior to providing consent; greater than 34 weeks' gestation; and unable to communicate in English with no translator available Setting: Canada.		
Interventions	Low-GI diet group (n = 13): participants were asked to select their starch choices from an exchange list of low-GI foods Intermediate or high-GI diet group (n = 16): participants were asked to select their starch choices from an exchange list of intermediate- and high-GI foods, reflecting the usual		

Grant 2011 (Continued)

	intake of typical DIP clinic patients All women: 1. standard Medical nutrition therapy: patients were introduced to the Diabetes Food Guide and Canadian dietary recommendations to support a healthy pregnancy. Clinic dietitian recommended how many starch choices/ servings each participant should consume at each mean based upon their own individual gestational energy requirements and Acceptable Macronutrient Distribution Ranges; 2. provision of approximately \$20/week worth of non-perishable study foods and all blood testing strips; 3. self-monitored blood glucose from baseline to week 8: 4 times a day (fasting, 2-h after breakfast, lunch and dinner); 4. insulin therapy if self-monitored blood glucose were not met with lifestyle modification within 2 to 3 weeks.
Outcomes	Primary outcomes: fasting serum glucose and HbA1c at baseline and 4 weeks after intervention; SMBG from baseline to week 8 Secondary outcomes: serum glucose, insulin, lipids and C-reactive protein at baseline and 4 weeks after intervention, maternal dietary intake, physical activity (time, type and duration), birthweight, use of insulin, macrosomia (birthweight \geq 4000 g), LGA (> 90th percentile population specific), SGA (< 10th percentile population specific)
Notes	CDA criteria used for GDM diagnosis: • fasting: 5.3 mmol/L; • 1-h 75-g OGTT: 10.6 mmol/L; • 2-h 75-g OGTT: 8.9mmol/L; • GDM: 2 of the values are met or exceeded.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation order was created by one of the investigators who was not involved in recruitment. It is unclear how the sequence was generated, but it is likely to be a computer-generated sequence
Allocation concealment (selection bias)	Low risk	Sealed, numbered, opaque envelopes were used, and various block sizes in randomisation were used
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Described as an "open-label" pilot study.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information on whether outcome assessors were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	3 women (10.3%) in the low-GI group withdrew after randomisation, reasons given. Data were analysed on an

Grant 2011 (Continued)

		intent-to-treat basis
Selective reporting (reporting bias)	High risk	Only limited data were reported on some of the prespecified review outcomes
Other bias	Low risk	There is no obvious risk of other bias.

Lauszus 2001

Methods	Randomised controlled trial.
Participants	N = 27. Women with a positive 3-hour 75 g OGTT before the 34 weeks' gestation Exclusion criteria: use of any hypoglycaemic, anti-lipidaemic or antihypertensive medication
Interventions	High-carbohydrate diet group (n = 14): from 34 weeks' gestation women had a high carbohydrate diet, no details about high carbohydrate diet High-monounsaturated fat diet group (n = 13): from 34 weeks' gestation women had a high-monounsaturated fat diet, no details about high-monounsaturated fat diet All women: after being diagnosed with GDM, all women were instructed to follow a high-carbohydrate diet until the 34 th week.
Outcomes	Pre-eclampsia, glycaemic control, insulin sensitivity, gestational weight change, maternal postpartum BMI, macrosomia, LGA, birthweight, gestational age at birth, postpartum development of diabetes mellitus
Notes	GDM diagnosis based on 3-h 75 grams OGTT, bloods taken every 30 min; GDM was defined as 2 or more plasma glucose samples above three standard deviations of the mean

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Reported as "the randomisation was performed blockwise stratified for pre-pregnancy weight with an expected ratio of obese to normal weight of three to one. The block sizes were six and two in the two strata"
Allocation concealment (selection bias)	Low risk	Reported as that "the randomisation was performed by a third person at an independent centre outside our institution, which produced information about the outcome of randomisation at baseline measurement in week 33"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	It was not feasible to blind study participants. No information on whether research personnel were blinded or not

Lauszus 2001 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information on whether outcome assessors were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data were missing at multiple collection points for 1 to 2 patients but this was explained in the text and is unlikely to affect the results for perinatal outcomes
Selective reporting (reporting bias)	High risk	Most of the prespecified review outcomes were not reported in this trial
Other bias	High risk	Women in the high-monounsaturated fat diet group had a higher trial entry BMI (mean [SD]: 35 [2.4] kg/m 2) when compared with women in the high-carbohydrate group (mean [SD]: 32.2 [1.5] kg/m 2).

Louie 2011

Methods	Randomised controlled trial.
Participants	N = 92. Women aged at 18-45 years, diagnosed with GDM by a 75 g OGTT between 20 and 32 weeks' gestation according to ADIPS criteria (see notes), with an otherwise healthy singleton pregnancy Exclusion criteria: women who had special dietary requirements (including vegetarianism/veganism), pre-existing diabetes, or pregnancy achieved by assisted reproduction and those who smoked or consumed alcohol during pregnancy Setting: Australia.
Interventions	Low-GI diet group (n = 50): diet GI target of ≤ 50, other nutrients were the same as the comparison group High-fibre moderate-GI diet (n = 49): diet GI target of around 60, which represented average GI of Australian population All women: 1. healthy diets of similar protein (15% to 25% total daily energy intake), fat (25% to 30% total daily energy intake), and carbohydrate (40% to 45% total daily energy intake) content; 2. completed 3-day food record (2 weekdays and 1 weekend day) at baseline and 36-37 weeks' gestation; 3. received 2 food model booklet to assist in portion size estimation.
Outcomes	Pregnancy outcomes: birthweight, the need for emergency caesarean section, gestational age at birth, macrosomia, SGA, LGA, ponderal index, neonatal anthropometry (length, head circumference), maternal metabolic profile in GDM
Notes	 68% participants in this trial had a BMI < 25 kg/m². Insulin treatment was commenced if the mean fasting BGL or 1-h postprandial BGL in the preceding week exceeded 5.2 and 7.5 mmol/L, respectively.

Louie 2011 (Continued)

- 3. Self-reported pre-pregnancy weight; last weight before delivery was obtained from medical record.
 - 4. ADIPS criteria used for GDM diagnosis:
 - fasting BGL \geq 5.5 mmol/L;
 - 2-hour BGL after 75 g glucose load ≥ 8.0 mmol/L;
 1 or more value(s) is (are) met or exceeded.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Described as "the enrolled subjects were centrally ran- domised to study diet by computer generated random numbers, stratified by BMI and weeks of gestation"
Allocation concealment (selection bias)	Low risk	Described as "the allocation sequence was unpredictable and concealed from the recruiter"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Reported that (besides research dietitian who provided trial intervention) all study personnel and participants were blinded to dietary assignment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Reported that the unblinded research dietitian was involved in data collection, no other information on whether or not other outcome assessors were blinded to group allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	In the low-GI group, 1 woman was excluded due to incorrect GDM diagnosis, 3 women withdraw after intervention, 2 women had preterm births, leaving 44 women who completed the study, and 47 women were included in analysis In high-fibre group, 2 women withdrew after group allocation, another 2 women withdrew after intervention; 2 women had preterm births, leaving 43 women who completed the study and 45 women who were included in analysis
Selective reporting (reporting bias)	High risk	Only limited data were reported on some of the prespecified review outcomes
Other bias	High risk	At baseline, 2-hour post 75 g glucose load BGL for women in low-GI group were significantly higher than those in conventional high-fibre group (mean [SD]: low-GI 8.6 [1.2] mmol/L vs high-fibre group 8.0 [1.3] mmol/L; P = 0.024)

Magee 1990

Methods	Randomised controlled trial.
Participants	N = 12. Obese women (defined as: pre-pregnancy weight > 120% of ideal body weight as specified by the Corrected 1959 Metropolitan Life Insurance table) with GDM according to ADA criteria (see notes) Exclusion criteria: not reported. Setting: the United States.
Interventions	During the second hospitalised week: Energy-restricted diet group (n = 7): on an energy-restricted diet of 1200 kcal/day diet by reducing serving size without changing the pattern and content of the diet in the first hospitalised week No energy restriction diet group (n = 5): continue the standard diet prescribed as the first week, for about 2400 kcal/day All women: hospitalised for the 2 weeks duration. Studies and diet during the first week were identical for all patients During the first hospitalised week: 1. dietary pattern: 25% total energy for breakfast, lunch and dinner. 12.5% total energy for afternoon tea and supper; 2. diet contents were: 50% carbohydrate, 30% fat, 20% protein, with 11 g of total dietary fibre per 500kcal; 3. daily morning double-voided urine sample for ketone and fasting plasma glucose; 4. on the sixth day of each week: blood after overnight fast for plasma glucose, insulin, triglyceride, free fatty acids, glycerol, β -hydroxhbutyrate. A glucose profile with 25 samples drawn over 24 hrs was initiated as well on the same day; 5. on the seventh day of each week: repeat fasting blood work as day 6 and a 3-h 100-g OGTT.
Outcomes	Metabolic profile including plasma glucose, fasting plasma insulin, urine ketones
Notes	ADA criteria used for GDM diagnosis: • 2 or more values meeting the following in 100g 3-h OGTT; • fasting 5.3 mmol/L; • 1-h: 10 mmol/L; • 2-h: 8.6 mmol/L; • 3-h: 7.8 mmol/L.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as "subjects were randomised to the control or calorie-restricted group"
Allocation concealment (selection bias)	Unclear risk	No information was given on allocation concealment.

Magee 1990 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No information on whether participants or research personnel were blinded or not
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information on whether outcome assessors were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up or post randomisation exclusions
		reported
Selective reporting (reporting bias)	High risk	None of the clinical outcomes prespecified in this review was reported

Moses 2009

Methods	Randomised controlled trial.
Participants	N = 63. Women aged at 18 to 40 years (inclusive) diagnosed with GDM according to ADIPS criteria (see notes), singleton pregnancy, no previous GDM, non-smoker, and seen for the first dietary visit between 28 and 32 weeks of gestation, and ability to follow the protocol requirements Exclusion criteria: any condition or medication that could affect glucose levels and unwillingness to follow the prescribed diet Setting: Australia.
Interventions	Low-GI diet group (n = 31): diet based on previously verified low-glycaemic index food, including pasta, grain breads, and unprocessed breakfast cereals with a high-fibre content. Women were specifically asked to avoid consuming white bread, processed commercial breakfast cereals, potatoes, and some rice varieties Conventional high-fibre, low-sugar, higher-GI diet group (n = 32): women were advised to follow a diet with a high-fibre and low-sugar content, with no specific mention of the GI. Potatoes, whole wheat bread, and specific high-fibre, moderate-to-high GI breakfast cereals were recommended All women: 1. were provided with a home glucose meter and were asked to test after fasting and 1 hour after the start of each of their 3 major meals at least every second day; 2. had at least 4 times diabetes centre visit with dietitian for dietary assessment and if they required insulin were seen as many times as necessary for insulin adjustment; 3. were provided with a booklet outlining the carbohydrate choices the carbohydrate food amounts constituting 1 serving (based on 15 g portions); 4. were advised to consume 3 small meals and 2 to 3 snacks with a specified number of servings of carbohydrate.

Moses 2009 (Continued)

Outcomes	Method of delivery, macrosomia, LGA, induction of labour, preterm birth, birthweight, infant anthropometric outcomes, Apgar score
Notes	ADIPS criteria used for GDM diagnosis: • fasting BGL ≥ 5.5 mmol/L; • 2-hour BGL after 75 g glucose load ≥ 8.0 mmol/L; • 1 or more value(s) is (are) met or exceeded.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Described as: "participants were randomly assigned to receive one of two different diets using permuted blocks of unequal size with the list generated using STATA (Version 7.0)"
Allocation concealment (selection bias)	Low risk	Method of generation of randomisation sequence likely to have concealed allocation
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants and study dietitian were not blinded. The physician caring for the patients was blinded to group allocation
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information on whether outcome assessors were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up or post randomisation exclusion.
Selective reporting (reporting bias)	High risk	Most of the prespecified review outcomes were not reported in this trial
Other bias	Low risk	There is no obvious risk of other bias.

Rae 2000

Methods	Randomised controlled trial.
Participants	N = 125; N = 117 women involved in analysis (8 withdraw). Women at \leq 35 weeks 6 days gestation; > 110% of ideal body weight for height (adjusted for expected pregnancy weight gain and using a BMI of 25 as equal to 100% ideal body weight); fasting BGL > 5.4 mmol/L and or 2 hour BGL > 7.9 mmol/L in 75 g 2 hour OGTT Exclusion criteria: not reported. Setting: Australia.

Interventions	Energy-restricted diet group (30% energy restriction) (n = 67 with outcome data available for 63 women): women on a diabetic diet providing between 6800 and 7600 kJ energy per day, which represented 70% of the Recommended Dietary Intake for pregnancy women (National Health and Medical Research Council of Australia) No energy restriction diet group (n = 58 with outcome data available for 54 women): women on diabetic diet without energy restriction, providing 8600 to 9500 kJ energy per day All women: 1. diabetes education provided by a research dietitian at each antenatal visit; 2. hyperglycaemia control, BGL self-monitoring: before and 2 hours after each meal (6 times per day), for a minimum of 2 days each week; 3. fetal and maternal surveillance and anticipated term delivery; 4. use of insulin decided by medical staffs that were blinded to group allocation. Criteria for insulin: fasting BGL > 5.5 mmol/L or 2-h BGL > 7.0 mmol/L on two or more occasions in any 72 hours period at the same pre- or post-prandial epoch; 5. metabolic monitoring for HbA1c, serum beta-hydroxybutyrate, urinary ketone; 6. 3-day food intake dairies for adherence to diet.
Outcomes	Macrosomia, newborns anthropometric measurement at 5 days of age, maternal dietary intake
Notes	 Women's BMI at GDM diagnosis mean [SD] was 37.9 [0.7] and 38.9 [0.7] for women in intervention group and control group, respectively. Due to the adherence to the dietary intervention, there was no significant difference in total energy intake between groups. 7 sets of twins were included in the study, 3 sets in the intervention group and 4 sets in the control group.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Described as "women were allocated at random by draw of opaque numbered envelopes"
Allocation concealment (selection bias)	Unclear risk	Described as above. It is likely adequately done.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants and diabetes service staff were blinded to allocation to diet group
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Described as that "demographic, obstetric and neonatal data were collected prospectively'. No information on whether or not outcome assessors were blinded to group allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	A total of 8 women (6.4%) (four from each group) with- drew and were excluded from data analysis; reasons for withdraw and baseline details about these eight women

Rae 2000 (Continued)

		were not given Some data points have small numbers of lost participants that are unexplained in the text, although this is unlikely to have affected the overall results.
Selective reporting (reporting bias)	High risk	Most of the prespecified review outcomes were not reported in this trial Outcomes including shoulder dystocia, birthweight, gestational age at birth were reported in one trial. However, as it was unclear about the sample sizes in each study groups for each of these reported outcomes, hence, no data were able to be included in the review
Other bias	Low risk	There is no obvious risk of other bias.

Reece 1995

Methods	Randomised controlled trial.
Participants	N = 22. Women diagnosed with GDM between 24-29 weeks' gestation. Exclusion criteria: diagnosis of GDM after 29 weeks' gestation Setting: United States.
Interventions	ADA diet group (n = 11): diet containing 20 g fibre per day; 30% daily energy intake derived from fat, and 50% derived from carbohydrate Fibre-enriched diet group (n = 11): diet containing 80 g fibre per day; 20% daily energy intake derived from fat, and 60% derived from carbohydrate All women: capillary BGL 6 times a day (before and after each meal), twice weekly
Outcomes	Gestational weight gain, insulin required for hyperglycaemia, birthweight, gestational age at birth
Notes	GDM diagnostic criteria not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection Low risk Randomisation table.		Randomisation was done by using a random numbers table.	
Allocation concealment (selection bias)	Unclear risk	Not reported.	
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were unlikely to be blinded. The research dietitian and the diabetes nurse specialis who were responsible for monitoring diet compliance.	

Reece 1995 (Continued)

		and glycaemic control were unlikely to be blinded Unclear about whether other research personnel were blinded or not
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information on whether outcome assessors were blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Women with insulin-dependent diabetes and GDM were included in the trial. It was reported that 11/61 women (5 in the ADA diet group and 6 in the fibre-enriched diet) were excluded from the study after randomisation: one had a spontaneous abortion, 2 moved away, and 4 from each group were noncompliant It is unclear how many of these 11 women excluded after randomisation were women with GDM
Selective reporting (reporting bias)	High risk	Most of the prespecified review outcomes were not reported in this trial
Other bias	Low risk	There is no obvious risk of other bias.

ADA: the American Diabetes Association

ADIPS: Australian Diabetes in Pregnancy Society

CDA: Canadian Diabetes Association

BGL: blood glucose level BMI: body mass index

GDM: gestational diabetes mellitus

GI: glycaemic index

HBGM: home blood glucose monitoring

LGA: large-for-gestational age

NIPerIER: National Institute of Perinatology Isidro Espinosa de los Reyes

OGTT: oral glucose tolerance test

SD: standard deviation

SGA: small-for-gestational age SMBG: self-monitored blood glucose T1DM: type 1 diabetes mellitus WHO: World Health Organization

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Gillen 2004	Study compared standard clinical care only for women with GDM with standard clinical care with additional advice targeting intakes of foods rich in unsaturated fats
Gillmer 1986	Study compared diet alone with diet and insulin for GDM management, did not meet the inclusion criteria of this review for interventions
Ilic 1999	Women in one group had a meal containing saturated fat and women in the other group had a meal containing monounsaturated fat. 2 weeks later, women in the 2 groups swapped to have the other group's meal Not meeting the inclusion criteria for eligible interventions for this review
Knopp 1991	A literature review on management of GDM.
Ma 2011	Participants were also instructed to increase exercise level by adding daily walking activity
Nolan 1984	A randomised cross-over study.
Reader 2006	Trial did not compare different types of dietary advice, but compared different types of care for women with GDM. Women in the intervention group were cared according to the nutrition practice guidelines for GDM, that emphasised 3 major areas of setting individualised medical nutrition therapy goals, BGL monitoring, a minimum of 3 nutrition visits with follow ups via phone or in person. Women in the control group received usual prenatal nutrition care

BGL: blood glucose level

GDM: gestational diabetes mellitus

DATA AND ANALYSES

Comparison 1. Low-moderate GI food versus high-moderate food

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Macrosomia (birthweight greater than 4000 g)	2	89	Risk Ratio (M-H, Fixed, 95% CI)	0.45 [0.10, 2.08]
2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age)	2	89	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.27, 3.36]
3 Caesarean section	1	63	Risk Ratio (M-H, Fixed, 95% CI)	0.66 [0.29, 1.47]
4 Operative vaginal birth	1	63	Risk Ratio (M-H, Fixed, 95% CI)	0.62 [0.16, 2.37]
5 Normal vaginal birth	1	63	Risk Ratio (M-H, Fixed, 95% CI)	1.35 [0.89, 2.07]
6 Birthweight (g)	1	62	Mean Difference (IV, Fixed, 95% CI)	-50.70 [-272.56, 171.16]
7 Gestational age at birth	1	62	Mean Difference (IV, Fixed, 95% CI)	0.30 [-0.30, 0.90]
8 Small-for-gestational age	1	63	Risk Ratio (M-H, Fixed, 95% CI)	5.16 [0.26, 103.27]
9 Induction of labour	1	63	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.33, 2.34]
10 Preterm birth (< 37 weeks' gestation)	1	63	Risk Ratio (M-H, Fixed, 95% CI)	0.52 [0.05, 5.41]
11 Insulin or oral hypoglycaemic agent required for hyperglycaemia	3	126	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.37, 1.93]

Comparison 2. Low-GI diet versus high-fibre moderate-GI diet

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Macrosomia (birthweight greater than 4000 g)	1	92	Risk Ratio (M-H, Fixed, 95% CI)	0.32 [0.03, 2.96]
2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age)	1	92	Risk Ratio (M-H, Fixed, 95% CI)	2.87 [0.61, 13.50]
3 Caesarean section	1	88	Risk Ratio (M-H, Fixed, 95% CI)	1.8 [0.66, 4.94]
4 Birthweight (g)	1	92	Mean Difference (IV, Fixed, 95% CI)	0.0 [-277.18, 277. 18]
5 Gestational age at birth (weeks)	1	92	Mean Difference (IV, Fixed, 95% CI)	-0.10 [-0.39, 0.19]
6 Preterm birth	1	92	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.14, 6.51]
7 Small-for-gestational age	1	92	Risk Ratio (M-H, Fixed, 95% CI)	1.20 [0.34, 4.18]
8 Ponderal index (kg/m ³)	1	92	Mean Difference (IV, Fixed, 95% CI)	0.20 [-0.79, 1.19]
9 Weight gain during pregnancy (kg)	1	87	Mean Difference (IV, Fixed, 95% CI)	-1.20 [-3.43, 1.03]
10 Adherence to dietary intervention	1	92	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.64, 1.11]

Comparison 3. Energy-restricted diet versus no energy restriction diet

Outcome or subgroup title	No. of No. of studies participants		Statistical method	Effect size
1 Fetal mortality	1	124	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Macrosomia	1	122	Risk Ratio (M-H, Fixed, 95% CI)	1.56 [0.61, 3.94]
3 Large-for-gestational age	1	123	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [0.65, 2.12]
4 Caesarean section	1	121	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.74, 1.89]
5 Operative vaginal birth	1	121	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.38, 2.54]
6 Normal vaginal birth	1	121	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.63, 1.27]
7 Induction of labour	1	114	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.68, 1.53]
8 Pre-eclampsia	1	117	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.51, 1.97]
9 Insulin or oral hypoglycaemic agent required for hyperglycaemia	1	117	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.47, 2.34]
10 Insulin sensitivity	1		Std. Mean Difference (IV, Fixed, 95% CI)	Subtotals only
10.1 Fasting plasma glucose (mmol)	1	12	Std. Mean Difference (IV, Fixed, 95% CI)	-0.35 [-1.51, 0.81]
10.2 Fasting plasma insulin (pM)	1	12	Std. Mean Difference (IV, Fixed, 95% CI)	-0.17 [-1.32, 0.98]

Comparison 4. Low-carbohydrate (CHO) diet (\leq 45% total energy from CHO) versus high-CHO diet (\geq 50% total energy from CHO)

Outcome or subgroup title	No. of No. of studies participants		Statistical method	Effect size		
1 Macrosomia (birthweight greater than 4000 g)	1	30	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]		
2 Caesarean section	1	30	Risk Ratio (M-H, Fixed, 95% CI)	1.4 [0.57, 3.43]		
3 Operative vaginal birth	1	30	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.07, 14.55]		
4 Normal vaginal birth	1	30	Risk Ratio (M-H, Fixed, 95% CI)	0.78 [0.39, 1.54]		
5 Birthweight (g)	1	30	Mean Difference (IV, Fixed, 95% CI)	22.0 [-241.06, 285. 06]		
6 Gestational age at birth (weeks)	1	30	Mean Difference (IV, Fixed, 95% CI)	0.10 [-0.83, 1.03]		

Comparison 5. High-monounsaturated fat (MUFA) diet ($\geq 20\%$ total energy from MUFA) versus high-CHO diet ($\geq 50\%$ total energy from CHO)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Macrosomia (birthweight greater than 4000 g)	1	27	Risk Ratio (M-H, Fixed, 95% CI)	0.65 [0.19, 2.18]
2 Large-for-gestational age	1	27	Risk Ratio (M-H, Fixed, 95% CI)	0.54 [0.21, 1.37]
3 Birthweight (g)	1	27	Mean Difference (IV, Fixed, 95% CI)	1.0 [-112.85, 114. 85]
4 Gestational age at birth (weeks)	1	27	Mean Difference (IV, Fixed, 95% CI)	0.10 [-0.13, 0.33]
5 Pre-eclampsia	1	27	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Insulin or oral hypoglycaemic agent required for hyperglycaemia	1	27	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Maternal weight at late pregnancy (third trimester) (kg)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
7.1 Maternal weight at 36 weeks' gestation	1	27	Mean Difference (IV, Fixed, 95% CI)	12.60 [7.93, 17.27]
7.2 Maternal weight at 38 weeks' gestation	1	27	Mean Difference (IV, Fixed, 95% CI)	11.80 [7.23, 16.37]
7.3 Maternal weight at delivery	1	27	Mean Difference (IV, Fixed, 95% CI)	11.90 [7.47, 16.33]
8 Maternal BMI at late pregnancy (third trimester) (kg/m ²)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
8.1 Maternal BMI at 36 weeks' gestation (kg/m ²)	1	27	Mean Difference (IV, Fixed, 95% CI)	4.70 [3.18, 6.22]
8.2 Maternal BMI at 38 weeks' gestation (kg/m ²)	1	27	Mean Difference (IV, Fixed, 95% CI)	3.80 [2.22, 5.38]
8.3 Maternal BMI at delivery (kg/m ²)	1	27	Mean Difference (IV, Fixed, 95% CI)	3.90 [2.41, 5.39]
9 Maternal postpartum BMI (> 4 months postpartum) (kg/m ²)	1	27	Mean Difference (IV, Fixed, 95% CI)	4.10 [2.34, 5.86]
10 Development of type 2 diabetes	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
10.1 Diagnosed by OGTT at early postnatal period (within 6 weeks postpartum)	1	24	Risk Ratio (M-H, Fixed, 95% CI)	2.0 [0.45, 8.94]
10.2 Diagnosed by OGTT at ≥ 4 months postpartum	1	6	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.10, 9.61]
11 Development of glucose intolerance without meeting type 2 diabetes diagnostic criteria	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
11.1 Diagnosed by OGTT at early postnatal period (within 6 weeks postpartum)	1	24	Risk Ratio (M-H, Fixed, 95% CI)	1.5 [0.30, 7.43]
11.2 Diagnosed by OGTT at ≥ 4 months postpartum	1	7	Risk Ratio (M-H, Fixed, 95% CI)	0.27 [0.01, 4.93]

Comparison 6. Standard ADA diet (20 g fibre/day) versus fibre-enriched diet (80 g fibre/ day)

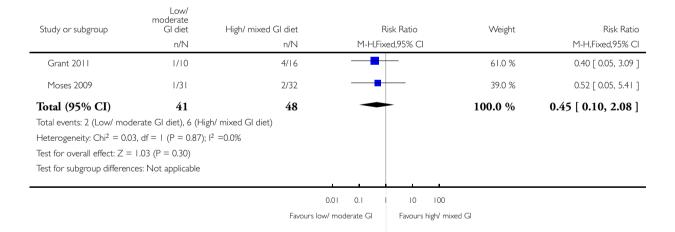
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Birthweight (g)	1	22	Mean Difference (IV, Fixed, 95% CI)	-94.0 [-446.71, 258. 71]
2 Gestational age at birth (weeks)	1	22	Mean Difference (IV, Fixed, 95% CI)	0.0 [-1.30, 1.30]
3 Insulin or oral hypoglycaemic agent required for hyperglycaemia	1	22	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Gestational weight gain (kg)	1	22	Mean Difference (IV, Fixed, 95% CI)	2.40 [-2.20, 7.00]

Analysis I.I. Comparison I Low-moderate GI food versus high-moderate food, Outcome I Macrosomia (birthweight greater than 4000 g).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: I Low-moderate GI food versus high-moderate food

Outcome: I Macrosomia (birthweight greater than 4000 g)

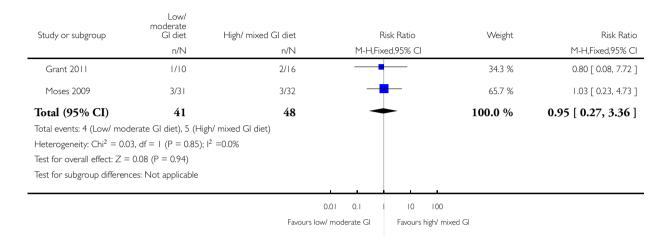


Analysis 1.2. Comparison I Low-moderate GI food versus high-moderate food, Outcome 2 Large-forgestational age (birthweight \geq 90th percentile for gestational age).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: I Low-moderate GI food versus high-moderate food

Outcome: 2 Large-for-gestational age (birthweight ≥ 90th percentile for gestational age)

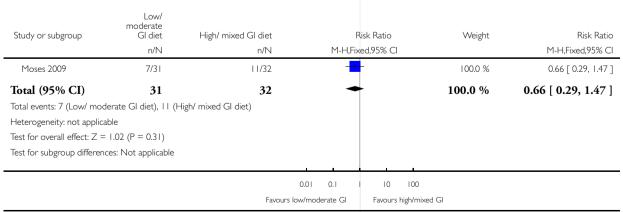


Analysis I.3. Comparison I Low-moderate GI food versus high-moderate food, Outcome 3 Caesarean section.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Outcome: 3 Caesarean section

Comparison: I Low-moderate GI food versus high-moderate food

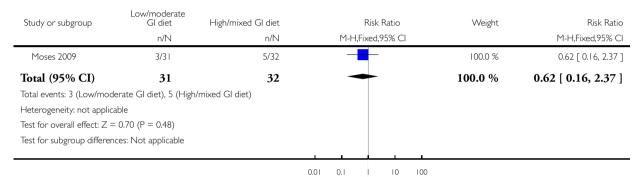


Analysis I.4. Comparison I Low-moderate GI food versus high-moderate food, Outcome 4 Operative vaginal birth.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: I Low-moderate GI food versus high-moderate food

Outcome: 4 Operative vaginal birth



Favours low/moderate GI

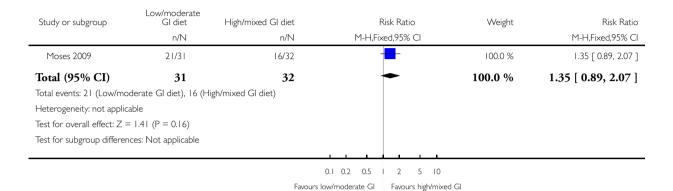
Favours high/mixed GI

Analysis 1.5. Comparison I Low-moderate GI food versus high-moderate food, Outcome 5 Normal vaginal birth.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: I Low-moderate GI food versus high-moderate food

Outcome: 5 Normal vaginal birth

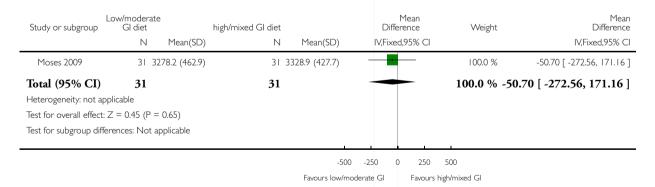


Analysis I.6. Comparison I Low-moderate GI food versus high-moderate food, Outcome 6 Birthweight (g).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: I Low-moderate GI food versus high-moderate food

Outcome: 6 Birthweight (g)

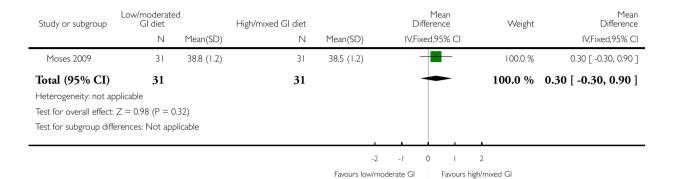


Analysis 1.7. Comparison I Low-moderate GI food versus high-moderate food, Outcome 7 Gestational age at birth.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: I Low-moderate GI food versus high-moderate food

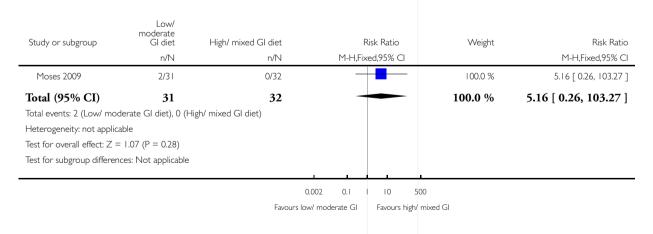
Outcome: 7 Gestational age at birth



Analysis I.8. Comparison I Low-moderate GI food versus high-moderate food, Outcome 8 Small-forgestational age.



Outcome: 8 Small-for-gestational age

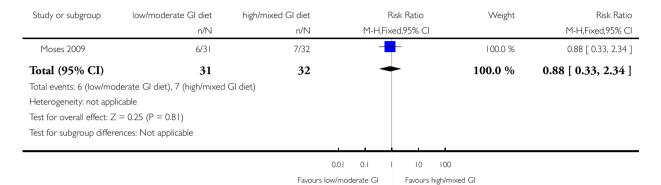


Analysis 1.9. Comparison I Low-moderate GI food versus high-moderate food, Outcome 9 Induction of labour.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: I Low-moderate GI food versus high-moderate food

Outcome: 9 Induction of labour

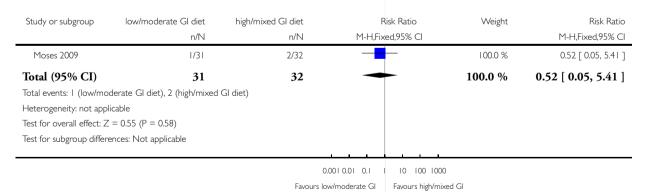


Analysis 1.10. Comparison I Low-moderate GI food versus high-moderate food, Outcome 10 Preterm birth (< 37 weeks' gestation).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: I Low-moderate GI food versus high-moderate food

Outcome: 10 Preterm birth (< 37 weeks' gestation)



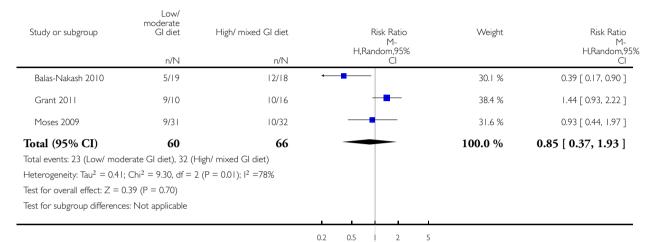
Different types of dietary advice for women with gestational diabetes mellitus (Review) Copyright © 2013 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Analysis I.II. Comparison I Low-moderate GI food versus high-moderate food, Outcome II Insulin or oral hypoglycaemic agent required for hyperglycaemia.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: I Low-moderate GI food versus high-moderate food

Outcome: II Insulin or oral hypoglycaemic agent required for hyperglycaemia



Favours low/ moderate GI

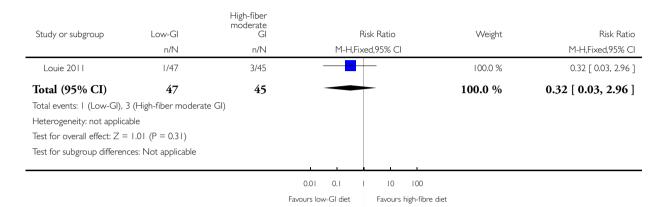
Favours high/ mixed GI

Analysis 2.1. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome I Macrosomia (birthweight greater than 4000 g).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 2 Low-GI diet versus high-fibre moderate-GI diet

Outcome: I Macrosomia (birthweight greater than 4000 g)

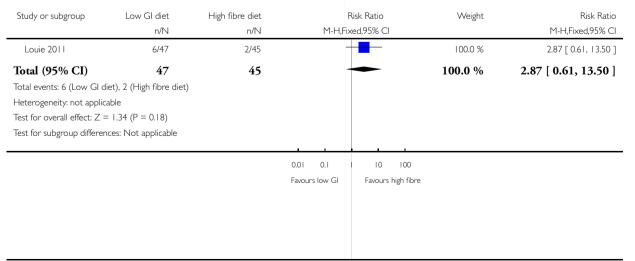


Analysis 2.2. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 2 Large-forgestational age (birthweight \geq 90th percentile for gestational age).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 2 Low-GI diet versus high-fibre moderate-GI diet

Outcome: 2 Large-for-gestational age (birthweight \geq 90th percentile for gestational age)

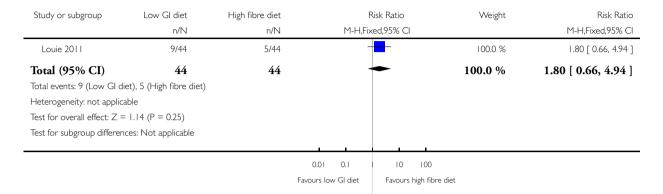


Analysis 2.3. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 3 Caesarean section.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 2 Low-GI diet versus high-fibre moderate-GI diet

Outcome: 3 Caesarean section

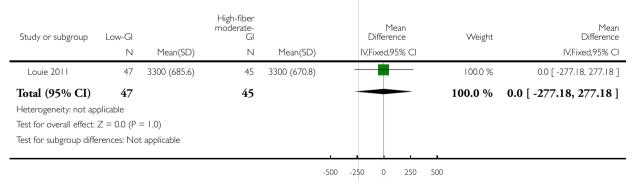


Analysis 2.4. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 4 Birthweight (g).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 2 Low-GI diet versus high-fibre moderate-GI diet

Outcome: 4 Birthweight (g)



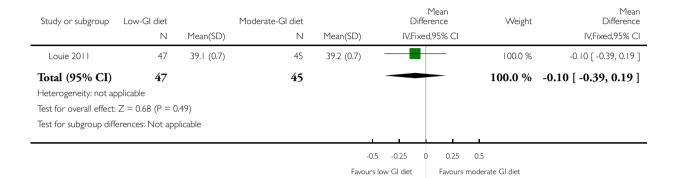
Favours low-GI diet Favours high-fiber diet

Analysis 2.5. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 5 Gestational age at birth (weeks).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 2 Low-GI diet versus high-fibre moderate-GI diet

Outcome: 5 Gestational age at birth (weeks)

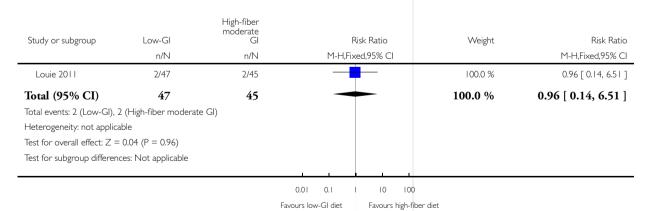


Analysis 2.6. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 6 Preterm birth.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 2 Low-GI diet versus high-fibre moderate-GI diet

Outcome: 6 Preterm birth

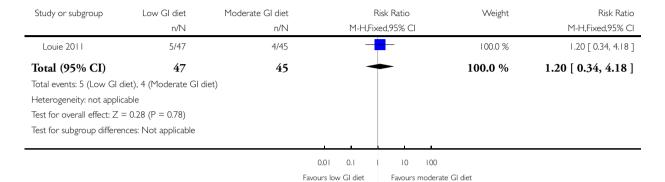


Analysis 2.7. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 7 Small-forgestational age.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 2 Low-GI diet versus high-fibre moderate-GI diet

Outcome: 7 Small-for-gestational age

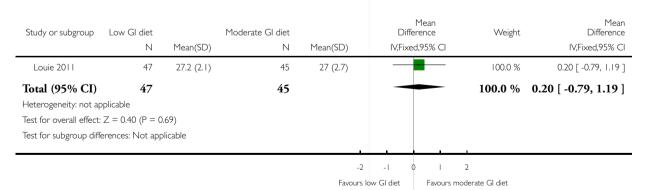


Analysis 2.8. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 8 Ponderal index (kg/m3).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 2 Low-GI diet versus high-fibre moderate-GI diet

Outcome: 8 Ponderal index (kg/m³)

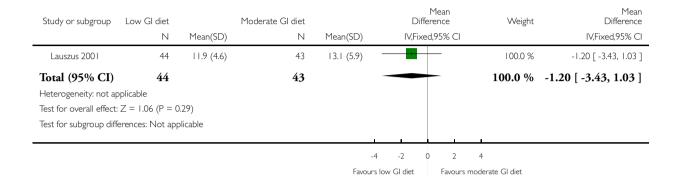


Analysis 2.9. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 9 Weight gain during pregnancy (kg).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 2 Low-GI diet versus high-fibre moderate-GI diet

Outcome: 9 Weight gain during pregnancy (kg)

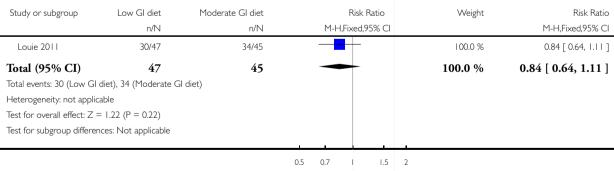


Analysis 2.10. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 10 Adherence to dietary intervention.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 2 Low-GI diet versus high-fibre moderate-GI diet

Outcome: 10 Adherence to dietary intervention



Favours low GI diet

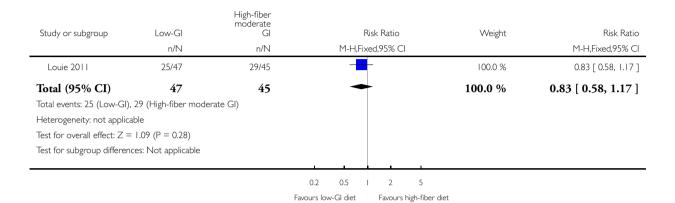
Favours moderate GI diet

Analysis 2.11. Comparison 2 Low-GI diet versus high-fibre moderate-GI diet, Outcome 11 Insulin required for hyperglycaemia.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 2 Low-GI diet versus high-fibre moderate-GI diet

Outcome: II Insulin required for hyperglycaemia



Analysis 3.1. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome I Fetal mortality.

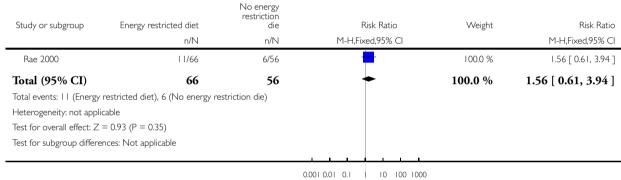
Review: Different types of dietary advice for women with gestational diabetes mellitus Comparison: 3 Energy-restricted diet versus no energy restriction diet Outcome: I Fetal mortality No energy restriction Study or subgroup Energy restricted diet Risk Ratio Weight Risk Ratio n/N n/N M-H,Fixed,95% CI M-H,Fixed,95% CI Rae 2000 0/66 0/58 Not estimable Total (95% CI) 66 58 Not estimable Total events: 0 (Energy restricted diet), 0 (No energy restriction die) Heterogeneity: not applicable Test for overall effect: not applicable Test for subgroup differences: Not applicable 0.01 0.1 100 10 Favours no energy

Analysis 3.2. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 2 Macrosomia.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 3 Energy-restricted diet versus no energy restriction diet

Outcome: 2 Macrosomia



0.001 0.01 0.1

Favours energy restricted

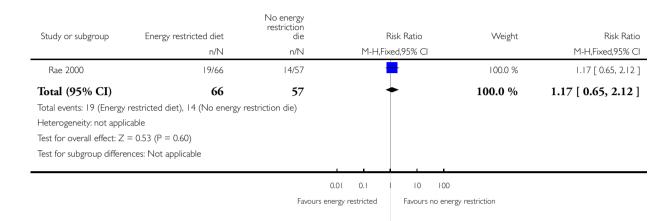
Favours no energy restriction

Analysis 3.3. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 3 Large-forgestational age.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 3 Energy-restricted diet versus no energy restriction diet

Outcome: 3 Large-for-gestational age

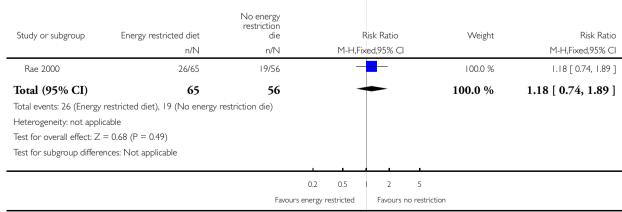


Analysis 3.4. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 4 Caesarean section.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 3 Energy-restricted diet versus no energy restriction diet

Outcome: 4 Caesarean section

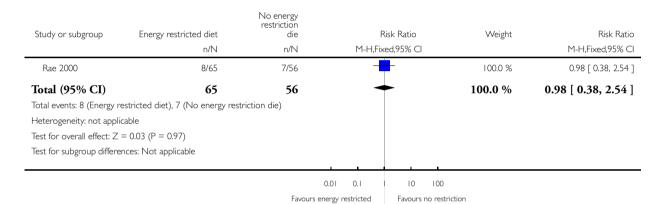


Analysis 3.5. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 5 Operative vaginal birth.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 3 Energy-restricted diet versus no energy restriction diet

Outcome: 5 Operative vaginal birth

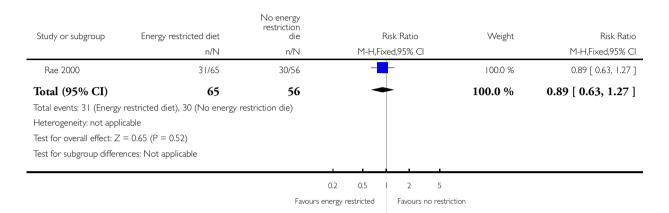


Analysis 3.6. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 6 Normal vaginal birth.

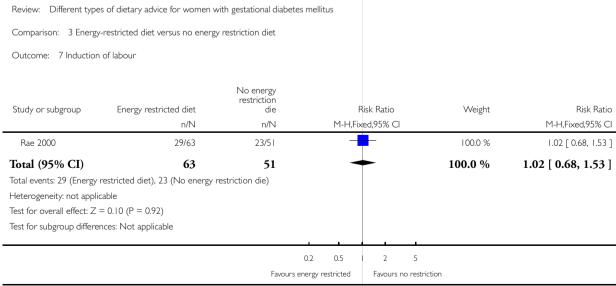
Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 3 Energy-restricted diet versus no energy restriction diet

Outcome: 6 Normal vaginal birth



Analysis 3.7. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 7 Induction of labour.

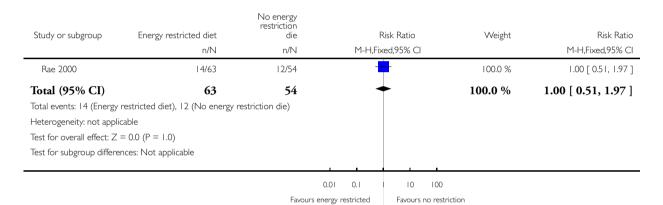


Analysis 3.8. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 8 Preeclampsia.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 3 Energy-restricted diet versus no energy restriction diet

Outcome: 8 Pre-eclampsia

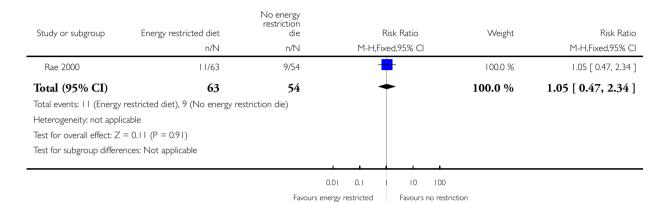


Analysis 3.9. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 9 Insulin or oral hypoglycaemic agent required for hyperglycaemia.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 3 Energy-restricted diet versus no energy restriction diet

Outcome: 9 Insulin or oral hypoglycaemic agent required for hyperglycaemia

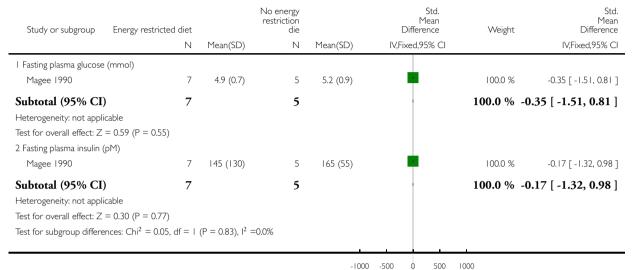


Analysis 3.10. Comparison 3 Energy-restricted diet versus no energy restriction diet, Outcome 10 Insulin sensitivity.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 3 Energy-restricted diet versus no energy restriction diet

Outcome: 10 Insulin sensitivity



-1000 -500 0 500 1000

Favours energy restricted

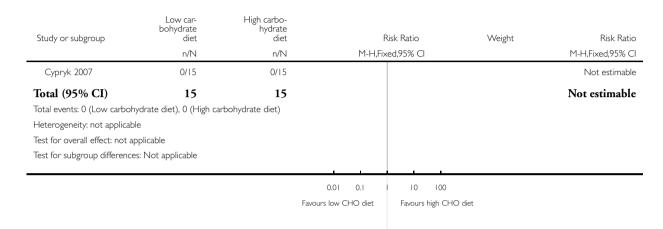
Favours no restriction

Analysis 4.1. Comparison 4 Low-carbohydrate (CHO) diet (\leq 45% total energy from CHO) versus high-CHO diet (\geq 50% total energy from CHO), Outcome I Macrosomia (birthweight greater than 4000 g).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 4 Low-carbohydrate (CHO) diet (\leq 45% total energy from CHO) versus high-CHO diet (\geq 50% total energy from CHO)

Outcome: I Macrosomia (birthweight greater than 4000 g)

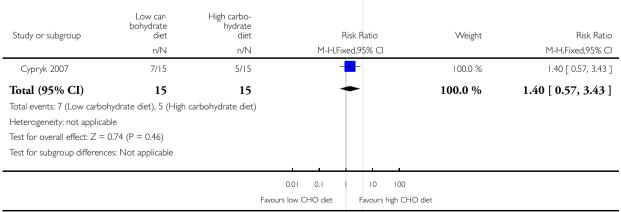


Analysis 4.2. Comparison 4 Low-carbohydrate (CHO) diet (≤ 45% total energy from CHO) versus high-CHO diet (≥ 50% total energy from CHO), Outcome 2 Caesarean section.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 4 Low-carbohydrate (CHO) diet (≤ 45% total energy from CHO) versus high-CHO diet (≥ 50% total energy from CHO)

Outcome: 2 Caesarean section

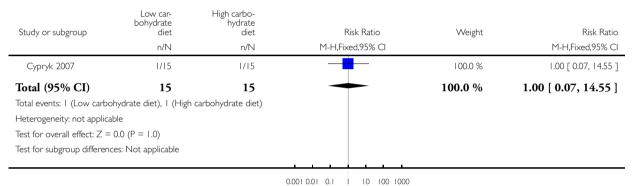


Analysis 4.3. Comparison 4 Low-carbohydrate (CHO) diet (≤ 45% total energy from CHO) versus high-CHO diet (≥ 50% total energy from CHO), Outcome 3 Operative vaginal birth.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 4 Low-carbohydrate (CHO) diet (\leq 45% total energy from CHO) versus high-CHO diet (\geq 50% total energy from CHO)

Outcome: 3 Operative vaginal birth



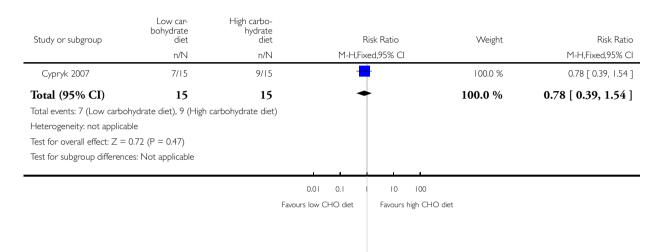
Favours low CHO diet Favours high CHO diet

Analysis 4.4. Comparison 4 Low-carbohydrate (CHO) diet (≤ 45% total energy from CHO) versus high-CHO diet (≥ 50% total energy from CHO), Outcome 4 Normal vaginal birth.

Review: Different types of dietary advice for women with gestational diabetes mellitus

 $\text{Comparison:} \quad \text{4 Low-carbohydrate (CHO) diet} \ (\leq 45\% \ \text{total energy from CHO)} \ \text{versus high-CHO diet} \ (\geq 50\% \ \text{total energy from CHO)}$

Outcome: 4 Normal vaginal birth

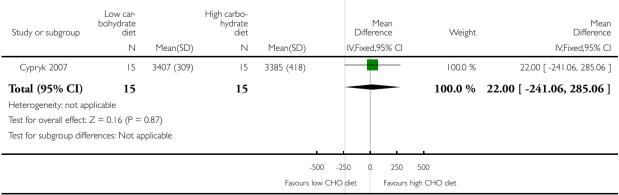


Analysis 4.5. Comparison 4 Low-carbohydrate (CHO) diet (≤ 45% total energy from CHO) versus high-CHO diet (≥ 50% total energy from CHO), Outcome 5 Birthweight (g).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 4 Low-carbohydrate (CHO) diet (\leq 45% total energy from CHO) versus high-CHO diet (\geq 50% total energy from CHO)

Outcome: 5 Birthweight (g)

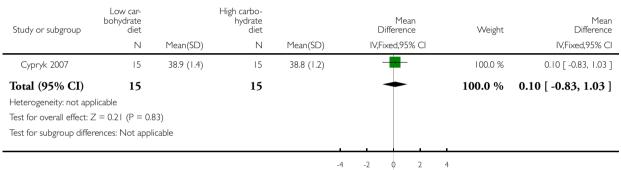


Analysis 4.6. Comparison 4 Low-carbohydrate (CHO) diet (\leq 45% total energy from CHO) versus high-CHO diet (\geq 50% total energy from CHO), Outcome 6 Gestational age at birth (weeks).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 4 Low-carbohydrate (CHO) diet (≤ 45% total energy from CHO) versus high-CHO diet (≥ 50% total energy from CHO)

Outcome: 6 Gestational age at birth (weeks)



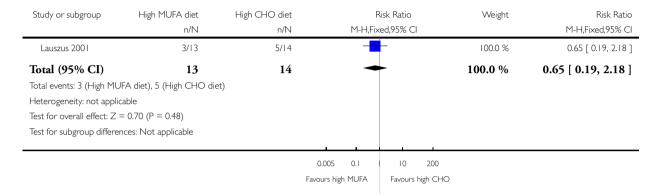
Favours low CHO diet Favours high CHO diet

Analysis 5.1. Comparison 5 High-monounsaturated fat (MUFA) diet (\geq 20% total energy from MUFA) versus high-CHO diet (\geq 50% total energy from CHO), Outcome I Macrosomia (birthweight greater than 4000 g).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO diet (≥ 50% total energy from CHO)

Outcome: I Macrosomia (birthweight greater than 4000 g)

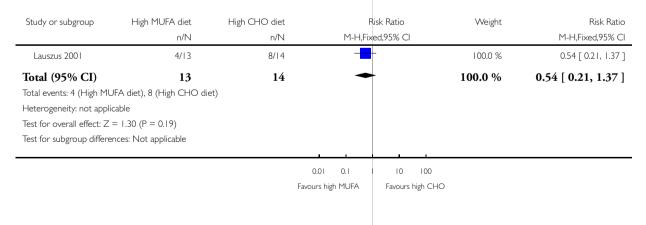


Analysis 5.2. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO diet (≥ 50% total energy from CHO), Outcome 2 Large-for-gestational age.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO diet (≥ 50% total energy from CHO)

Outcome: 2 Large-for-gestational age

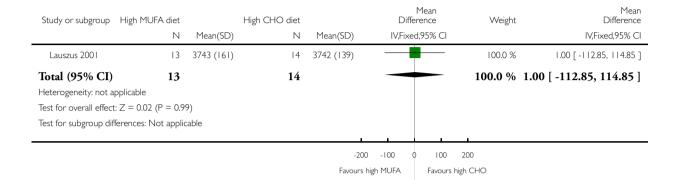


Analysis 5.3. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO diet (≥ 50% total energy from CHO), Outcome 3 Birthweight (g).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 5 High-monounsaturated fat (MUFA) diet (\geq 20% total energy from MUFA) versus high-CHO diet (\geq 50% total energy from CHO)

Outcome: 3 Birthweight (g)

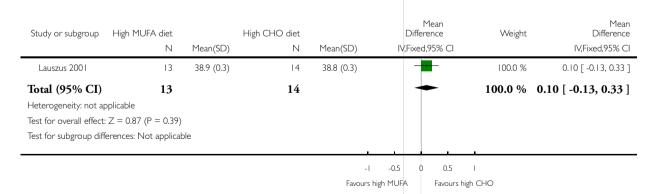


Analysis 5.4. Comparison 5 High-monounsaturated fat (MUFA) diet (\geq 20% total energy from MUFA) versus high-CHO diet (\geq 50% total energy from CHO), Outcome 4 Gestational age at birth (weeks).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO diet (≥ 50% total energy from CHO)

Outcome: 4 Gestational age at birth (weeks)

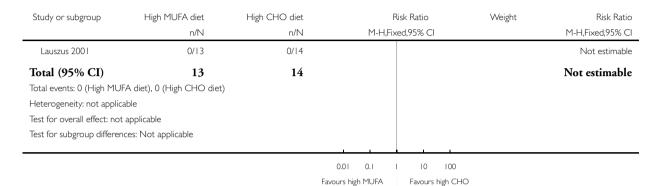


Analysis 5.5. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO diet (≥ 50% total energy from CHO), Outcome 5 Pre-eclampsia.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 5 High-monounsaturated fat (MUFA) diet (\geq 20% total energy from MUFA) versus high-CHO diet (\geq 50% total energy from CHO)

Outcome: 5 Pre-eclampsia



Analysis 5.6. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO diet (≥ 50% total energy from CHO), Outcome 6 Insulin or oral hypoglycaemic agent required for hyperglycaemia.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 5 High-monounsaturated fat (MUFA) diet (\geq 20% total energy from MUFA) versus high-CHO diet (\geq 50% total energy from CHO)

Outcome: 6 Insulin or oral hypoglycaemic agent required for hyperglycaemia

Study or subgroup	High MUFA diet	High CHO diet		Risk Ratio	Weight	Risk Ratio
	n/N		I*I-H,FI>	xed,95% CI		M-H,Fixed,95% CI
Lauszus 2001	0/13	0/14				Not estimable
Total (95% CI)	13	14				Not estimable
Total events: 0 (High MU	FA diet), 0 (High CHO diet)					
Heterogeneity: not applic	able					
Test for overall effect: not	t applicable					
Test for subgroup differer	nces: Not applicable					
			0.01 0.1	1 10 100		
		Fav	ours high MUFA	Favours high CH	10	

Analysis 5.7. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO diet (≥ 50% total energy from CHO), Outcome 7 Maternal weight at late pregnancy (third trimester) (kg).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO diet (≥ 50% total energy from CHO)

Outcome: 7 Maternal weight at late pregnancy (third trimester) (kg)

Study or subgroup	High MUFA diet N	Mean(SD)	High CHO diet	Mean(SD)	Mean Difference IV.Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
	11	r lean(3D)	14	rieari(3D)	17,1 (xed,75% C)		1v,i ixed,75% Ci
I Maternal weight at 36	weeks' gestation						
Lauszus 2001	13	100.1 (6.9)	14	87.5 (5.3)	-	100.0 %	12.60 [7.93, 17.27]
Subtotal (95% CI)	13		14		•	100.0 %	12.60 [7.93, 17.27]
Heterogeneity: not applie	cable						
Test for overall effect: Z	= 5.29 (P < 0.00001)					
2 Maternal weight at 38	weeks' gestation						
Lauszus 2001	13	100.3 (6.6)	14	88.5 (5.4)	-	100.0 %	11.80 [7.23, 16.37]
Subtotal (95% CI)	13		14		•	100.0 %	11.80 [7.23, 16.37]
Heterogeneity: not applie	cable						
Test for overall effect: Z	= 5.06 (P < 0.00001)					
3 Maternal weight at deli	very						
Lauszus 2001	13	100.5 (6.5)	14	88.6 (5.1)	-	100.0 %	11.90 [7.47, 16.33]
Subtotal (95% CI)	13		14		•	100.0 %	11.90 [7.47, 16.33]
Heterogeneity: not applie	cable						
Test for overall effect: Z	= 5.27 (P < 0.00001)					
Test for subgroup differe	nces: $Chi^2 = 0.07$, df	r = 2 (P = 0.97)	7), I ² =0.0%				
				1			

-20 -10 0 10 20
Favours high MUFA Favours high CHO

Analysis 5.8. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO diet (≥ 50% total energy from CHO), Outcome 8 Maternal BMI at late pregnancy (third trimester) (kg/m²).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO diet (≥ 50% total energy from CHO)

Outcome: 8 Maternal BMI at late pregnancy (third trimester) (kg/m²)

Mear nt Difference	Weight	Mean Difference		High CHO diet	High MUFA diet		Study or subgroup	
IV,Fixed,95% C		IV,Fixed,95% CI	Mean(SD)	Ν	Mean(SD)	Ν		
						eks' gestation (kg/m²)	I Maternal BMI at 36 wee	
% 4.70 [3.18, 6.22	100.0 %	_	31.5 (1.5)	14	36.2 (2.4)	13	Lauszus 2001	
6 4.70 [3.18, 6.22]	100.0 %	_		14		13	Subtotal (95% CI)	
						able	Heterogeneity: not applica	
						6.05 (P < 0.00001)	Test for overall effect: Z =	
						eks' gestation (kg/m²)	2 Maternal BMI at 38 wee	
% 3.80 [2.22, 5.38	100.0 %		32.2 (1.7)	14	36 (2.4)	13	Lauszus 2001	
6 3.80 [2.22, 5.38]	100.0 %	-		14		13	Subtotal (95% CI)	
						able	Heterogeneity: not application	
						= 4.72 (P < 0.00001)	Test for overall effect: Z =	
						y (kg/m²)	3 Maternal BMI at deliver	
% 3.90 [2.41, 5.39	100.0 %	_	32.4 (1.7)	14	36.3 (2.2)	13	Lauszus 2001	
6 3.90 [2.41, 5.39]	100.0 %			14		13	Subtotal (95% CI)	
						able	Heterogeneity: not applica	
						= 5.13 (P < 0.00001)	Test for overall effect: Z =	
				$I^2 = 0.0\%$	2 (P = 0.67)	ices: $Chi^2 = 0.80$, $df =$	Test for subgroup differen	

-4 -2 0 2 4
Favours high MUFA Favours high CHO

Analysis 5.9. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO diet (≥ 50% total energy from CHO), Outcome 9 Maternal postpartum BMI (> 4 months postpartum) (kg/m²).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO diet (≥ 50% total energy from CHO)

Outcome: 9 Maternal postpartum BMI (> 4 months postpartum) (kg/m²)

Study or subgroup	High MUFA diet		High CHO diet			Differe	ean nce	Weight	Mean Difference
	Ν	Mean(SD)	Ν	Mean(SD)	P	v,Fixed,9	5% CI		IV,Fixed,95% CI
Lauszus 2001	13	32.6 (2.8)	14	28.5 (1.7)			-	100.0 %	4.10 [2.34, 5.86]
Total (95% CI)	13		14					100.0 %	4.10 [2.34, 5.86]
Heterogeneity: not ap	plicable								
Test for overall effect:	Z = 4.56 (P < 0.000)	001)							
Test for subgroup diffe	erences: Not applicat	ole							
					-4 -2	0	2 4	1	

Favours high MUFA diet

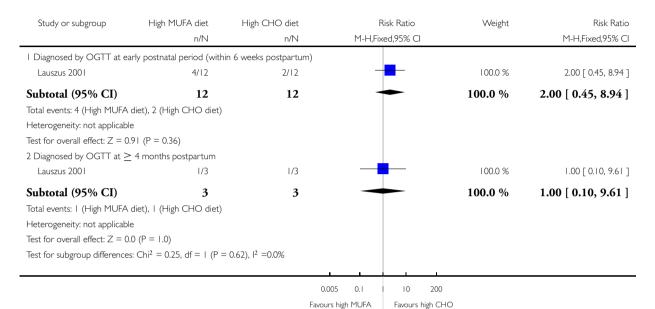
Favours high CHO diet

Analysis 5.10. Comparison 5 High-monounsaturated fat (MUFA) diet (\geq 20% total energy from MUFA) versus high-CHO diet (\geq 50% total energy from CHO), Outcome 10 Development of type 2 diabetes.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 5 High-monounsaturated fat (MUFA) diet (\geq 20% total energy from MUFA) versus high-CHO diet (\geq 50% total energy from CHO)

Outcome: 10 Development of type 2 diabetes

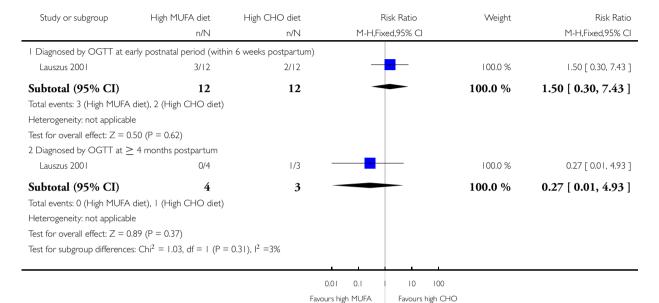


Analysis 5.11. Comparison 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO diet (≥ 50% total energy from CHO), Outcome 11 Development of glucose intolerance without meeting type 2 diabetes diagnostic criteria.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 5 High-monounsaturated fat (MUFA) diet (≥ 20% total energy from MUFA) versus high-CHO diet (≥ 50% total energy from CHO)

Outcome: II Development of glucose intolerance without meeting type 2 diabetes diagnostic criteria

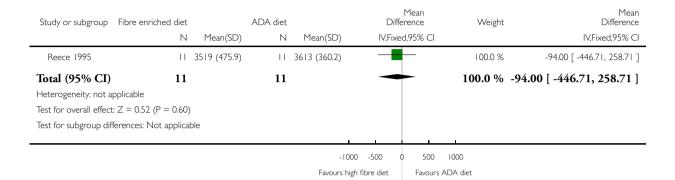


Analysis 6.1. Comparison 6 Standard ADA diet (20 g fibre/day) versus fibre-enriched diet (80 g fibre/ day), Outcome I Birthweight (g).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 6 Standard ADA diet (20 g fibre/day) versus fibre-enriched diet (80 g fibre/ day)

Outcome: I Birthweight (g)

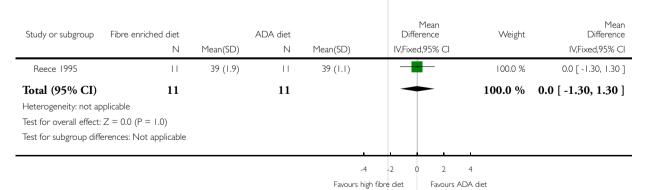


Analysis 6.2. Comparison 6 Standard ADA diet (20 g fibre/day) versus fibre-enriched diet (80 g fibre/ day),
Outcome 2 Gestational age at birth (weeks).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 6 Standard ADA diet (20 g fibre/day) versus fibre-enriched diet (80 g fibre/day)

Outcome: 2 Gestational age at birth (weeks)



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Analysis 6.3. Comparison 6 Standard ADA diet (20 g fibre/day) versus fibre-enriched diet (80 g fibre/ day), Outcome 3 Insulin or oral hypoglycaemic agent required for hyperglycaemia.

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 6 Standard ADA diet (20 g fibre/day) versus fibre-enriched diet (80 g fibre/ day)

Outcome: 3 Insulin or oral hypoglycaemic agent required for hyperglycaemia

Study or subgroup	Fibre enriched diet	ADA diet			Risk Ratio	Weight	Risk Ratio		
	n/N	n/N			M-H,Fixed,95% CI		xed,95% CI		M-H,Fixed,95% CI
Reece 1995	0/11	0/11					Not estimable		
Total (95% CI)	11	11					Not estimable		
Total events: 0 (Fibre enri	iched diet), 0 (ADA diet)								
Heterogeneity: not applic	able								
Test for overall effect: not	applicable								
Test for subgroup differen	nces: Not applicable								
			ı						
			0.01	0.1	1 10 100				

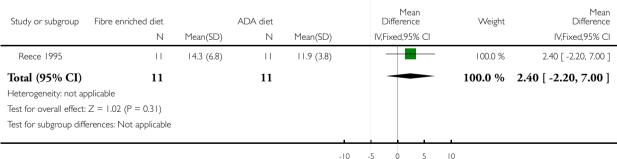
Favours high fibre diet Favours ADA diet

Analysis 6.4. Comparison 6 Standard ADA diet (20 g fibre/day) versus fibre-enriched diet (80 g fibre/ day), Outcome 4 Gestational weight gain (kg).

Review: Different types of dietary advice for women with gestational diabetes mellitus

Comparison: 6 Standard ADA diet (20 g fibre/day) versus fibre-enriched diet (80 g fibre/ day)

Outcome: 4 Gestational weight gain (kg)



Favours high fibre diet Favours ADA diet

APPENDICES

Appendix I. WOMBAT Perinatal Trials Registry search strategy

We searched trials in the Women and Babies Health and Wellbeing: Action through Trials (WOMBAT) Perinatal Trials Registry using the terms of "gestational diabetes mellitus", "pregnancy", "pregnant", "glucose intolerance", "diet", "dietary advice", "nutrition". We reviewed all relevant trials listed under the search results.

CONTRIBUTIONS OF AUTHORS

Shanshan Han wrote drafts of the protocol and review, with Caroline Crowther and Philippa Middleton contributing to data extraction, and commenting on and editing to all drafts. Emer Heatley was involved in data extraction and assessment of risk of bias of the included studies.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

• ARCH, Robinson Institute, The University of Adelaide, Australia.

External sources

- Australian Department of Health and Ageing, Australia.
- NHMRC: National Health and Medical Research Council, Australia.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Maternal secondary outcomes of maternal weight at late pregnancy (third trimester) and maternal BMI at late pregnancy (third trimester) were added.

INDEX TERMS

Medical Subject Headings (MeSH)

Caloric Restriction; Diabetes, Gestational [*diet therapy]; Diabetic Diet; Diet, Carbohydrate-Restricted; Dietary Carbohydrates [administration & dosage]; Dietary Fiber [administration & dosage]; Glycemic Index; Randomized Controlled Trials as Topic

MeSH check words Female; Humans; Pregnancy