MONASH University

Obesity, gestational weight gain and healthy lifestyle in pregnancy

by

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MBBS (Hons) FRACP

A thesis submitted for the degree of

Doctor of Philosophy

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School of Public Health and Preventive Medicine
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Abstract

Obesity presents a major public health and economic burden worldwide. Pregnancy is a key driver of weight gain and obesity, with most women in developed countries exceeding recommended gestational weight gain (GWG) with a mean 2-5kg retained per pregnancy (1-4). Obesity and excess GWG drive short-term and long-term adverse maternal and infant outcomes, including gestational diabetes (GDM), preterm birth, caesarean section, pre-eclampsia, large for gestational age (LGA), postpartum weight retention and childhood obesity (2, 5). Lifestyle interventions in pregnancy prevent excess GWG gain and reduce pregnancy complications (6-8). However, despite clear health needs and evidence for efficacy of lifestyle interventions, a major gap persists with inadequate translation of lifestyle change integrated into routine preconception and antenatal care.

The overarching theme of my PhD is to explore the effects of excess GWG and adverse maternal and infant health outcomes and the implementation of effective strategies to achieve healthy lifestyle and recommended weight gain in pregnancy. This includes evaluating experiences of high-risk women attending antenatal services, as well as health professionals' perspectives.

In chapter one, I summarised the existing literature on the prevalence, consequences and interventions for excess GWG. This enabled me to identify literature gaps that would inform further work in my PhD.

In chapter two, I evaluated the maternal and infant risks associated with weight gain outside of the 2009 Institute of Medicine (IOM) recommendations (2). In this international collaboration and systematic review and meta-analysis of more than one million women, 47% had GWG greater than IOM recommendations and 23% less than IOM recommendations. GWG below guideline recommendations was associated with a higher risk of small for gestational age (SGA) and preterm birth, and lower risk of LGA and macrosomia; whilst weight gain above guideline recommendations was associated with lower risk of SGA and preterm birth and higher risk of LGA, macrosomia and caesarean. This definitive work was published in JAMA and has been cited over 530 times at thesis submission. Here I also explored the impact of ethnicity on recommended weight GWG.

In chapter three, I developed, implemented and evaluated the Healthy Lifestyle in Pregnancy Project (HiPP) Monash Health, designed to limit GWG for women with obesity. This pragmatic implementation study was embedded within an existing maternity service. Evaluation included assessment of (1) GWG, maternal and infant outcomes, (2) health professionals' perspectives, and (3) pregnant women's experiences. Lifestyle intervention embedded in routine antenatal care lowered total GWG and GWG per week but did not alter proportion of women gaining above the recommended GWG. Intervention uptake and engagement rates were high, as were health professionals' and women's satisfaction and confidence.

In chapter four, I investigated satisfaction with diagnosis, risk perception and health beliefs to understand barriers and enablers of lifestyle change, to prevent type II diabetes post GDM. Results informed subsequent studies now underway internationally.

Finally, in chapter five – in an invited, published editorial – I summarised my findings, addressed strengths and limitations, and reviewed the gaps and future directions.

This thesis addresses important knowledge gaps in our understanding of GWG and obesity in pregnancy and generates new insights into risks associated with GWG outside of guidelines. It has contributed new knowledge in an innovative pragmatic trial, supported by implementation research. Findings have informed subsequent Horizons 2020 and NHMRC funded trials targeting implementation of lifestyle interventions in pregnancy.

Declaration

This thesis is an original work of my research and contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

Signature:

Print Name: Rebecca Goldstein

Date: 19/12/2020

Publications during enrolment

1. **Goldstein RF**, Teede HJ, Thangaratinam S, Boyle JA.
Excess Gestational Weight Gain in Pregnancy and the Role of Lifestyle Intervention
Seminars of Reproductive Medicine. 2016 Mar;34(2):e14-21. doi: 10.1055/s-0036-1583531. Epub 2016 May 24. [Chapter 1]
2018 impact factor 2.6

2. **Goldstein RF**, Abell SK, Ranasinha S, Misso M, Boyle J, Black MH, Li N, Hu G, Corrado F, Rode L, Kim YJ, Haugen M, Song W, Kim MH, Bogaerts A, Devlieger R, Chung JH, Teede HJ
Association of Gestational Weight Gain with Maternal and Infant Outcomes: A Systematic Review and Meta-analysis
The Journal of the American Medical Association (JAMA). 2017 Jun 6;317(21):2207-2225. doi: 10.1001/jama.2017.3635. [Chapter 2]
2018 impact factor 51.3; 530 citations

3. **Goldstein RF**, Abell SK, Ranasinha S, Misso ML, Boyle JA, Harrison CL, Black MH, Li N, Hu G, Corrado F, Hegaard H, Kim YJ, Haugen M, Song WO, Kim MH, Bogaerts A, Devlieger R, Chung JH, Teede HJ.
Gestational Weight Gain Across Continents and Ethnicity: Systematic Review and Meta-Analysis of Maternal and Infant Outcomes in More Than One Million Women
BMC Medicine. 2018 Aug 31;16(1):153. doi: 10.1186/s12916-018-1128-1. [Chapter 2]
2018 impact factor 8.3; 97 citations

4. **Goldstein RF**, Boyle JA, Cooray SD, Joham AE, Fitz-Gerald AL, Harrison CL, Teede HJ.
A Pragmatic Lifestyle Intervention Implemented into Antenatal Care to Optimise Lifestyle and Gestational Weight Gain for Women with Obesity: The Healthy Lifestyle in Pregnancy Project (HiPP)
Submitted Lancet Diabetes and Endocrinology. [Chapter 3]

5. **Goldstein RF**, Walker RE, Teede HJ, Harrison CL, Boyle JA.
The Healthy Pregnancy Service to Optimise Excess Gestational Weight Gain for Women with Obesity: A Qualitative Study of Health Professionals' Perspectives
Journal of Clinical Medicine 2020, 9(12), 4073. https://doi.org/10.3390/jcm9124073 [Chapter 3]
2019 impact factor 3.3

6. **Goldstein RF**, Boyle JA, Lo C, Teede HJ, Harrison CL.
Facilitators and Barriers to Behaviour Change Within a Lifestyle Program for Women with Obesity to Prevent Excess Gestational Weight Gain: A Mixed Methods Evaluation
Submitted Implementation Science. [Chapter 3]

7. **Goldstein RF**, Gibson-Helm ME, Boyle JA, Teede HJ.
Satisfaction with Diagnosis Process for Gestational Diabetes Mellitus and Risk Perception Among Australian Women
The International Journal of Gynecology and Obstetrics. 2015 Apr;129(1):46-9. doi: 10.1016/j.ijgo.2014.10.033. Epub 2015 Jan 6 [Chapter 4]
2018 impact factor 1.7

8. **Goldstein RF**, Harrison CL, Teede HJ.
Editorial: The Importance of Gestational Weight Gain
Obesity Reviews. 2020. PMID: 32608189 [Chapter 5]
2018 impact factor 8.2

Thesis including published works declaration

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

This thesis includes **six original papers published in peer-reviewed journals and two submitted publications**. The core theme of the thesis is **obesity, gestational weight gain and healthy lifestyle in pregnancy**. The ideas, development and writing up of all the papers in the thesis were the principal responsibility of myself, the student, working within the Monash Centre for Health Research and Implementation, School of Public Health and Preventive Medicine, Faculty of Medicine, Nursing and Health Sciences under the supervision of Professor Helena Teede, Associate Professor Jacqueline Boyle and Dr Cheryce Harrison.

The inclusion of co-authors reflects the fact that the work came from active collaboration between researchers and acknowledges input into team-based research.

In the case of chapters 1-5, my contribution to the work involved the following:

Thesis Chapter	**Publication Title**	**Status** *(published, in press, accepted or returned for revision, submitted)*	**Nature and % of student contribution**	**Co-author name(s) Nature and % of Co-author's contribution***	**Co-author(s), Monash student Y/N***
1	Excess Gestational Weight Gain in Pregnancy and the Role of Lifestyle Intervention	Published	75%: Primary responsibility for literature review and manuscript drafting	***Remaining authors***: 25% Helena Teede: input into manuscript Shakila Thangaratinam: input into manuscript Jacqueline Boyle: input into manuscript	 No No No
2	Association of Gestational Weight Gain with Maternal and Infant Outcomes: A Systematic Review and Meta-Analysis	Published	60%: Primary responsibility for data collection, analysis, interpretation and manuscript drafting	***Sally Abell***: 15% data collection, input into manuscript ***Helena Teede***: 15% study design, supervision of all aspects and input into manuscript	Yes No

				Remaining authors: 10% Sanjeeva Ranasinha: statistical analysis, input into manuscript Marie Misso: systematic review search, input into manuscript Jacqueline Boyle: input into manuscript All other authors: input into manuscript	 No No No No
2	Gestational Weight Gain Across Continents and Ethnicity: Systematic Review and Meta-Analysis of Maternal and Infant Outcomes in More Than One Million Women	Published	65%: Primary responsibility for data collection, analysis, interpretation and manuscript drafting	***Sally Abell***: 15% data collection, input into manuscript ***Helena Teede***: 15% study design, supervision of all aspects and input into manuscript ***Remaining authors: 5%*** Sanjeeva Ranasinha: statistical analysis, input into manuscript Marie Misso: systematic review search, input into manuscript Jacqueline Boyle: input into manuscript Cheryce Harrison: input into manuscript All other authors: input into manuscript	Yes No No No No No No
3	A Pragmatic Lifestyle Intervention Implemented into Antenatal Care to Optimise Lifestyle and Gestational Weight Gain for Women with Obesity: The Healthy Lifestyle in Pregnancy Project (HiPP)	Submitted	80%: Primary responsibility for data collection, analysis, interpretation and manuscript drafting	***Shamil Cooray***: 5% data collection and input into manuscript ***Remaining authors***: 15% Jacqueline Boyle: study design, analysis, supervision and input into manuscript	Yes No

				Anju Joham: study design and input into manuscript Allison Fitz-Gerald: input into manuscript Cheryce Harrison: study design, analysis, supervision and input into manuscript Helena Teede: study design, analysis, supervision and input into manuscript	No No No No
3	The Healthy Pregnancy Service to Optimise Excess Gestational Weight Gain for Women with Obesity: A Qualitative Study of Health Professionals' Perspectives	Published	85%: Primary responsibility for data collection, analysis, interpretation and manuscript drafting	***Remaining authors***: 15% Ruth Walker: data collection, analysis, interpretation and input into manuscript Helena Teede: input into manuscript Cheryce Harrison: study design, supervision and input into manuscript Jacqueline Boyle: study design, supervision and input into manuscript	 No No No No
3	Facilitators and Barriers to Behaviour Change Within a Lifestyle Program for Women with Obesity to Prevent Excess Gestational Weight Gain: A Mixed Methods Evaluation	Submitted	85%: Primary responsibility for data collection, analysis, interpretation and manuscript drafting	***Remaining authors***: 15% Clement Lo: data analysis and input into manuscript Jacqueline Boyle: study design, supervision and input into manuscript Helena Teede: input into manuscript Cheryce Harrison: study design, analysis, supervision and input into manuscript	 No No No No

4	Satisfaction with Diagnosis Process for Gestational Diabetes Mellitus and Risk Perception Among Australian Women	Published	85%: Primary responsibility for data analysis, interpretation and manuscript drafting	***Remaining authors***: 15% Melanie Gibson-Helm: data collection and input into manuscript Jacqueline Boyle: input into manuscript Helena Teede: study design, supervision and input into manuscript	No No No
5	Editorial: The Importance of Gestational Weight Gain	Published	75%: Primary responsibility for literature review and manuscript drafting	***Remaining authors***: 25% Cheryce Harrison: input into manuscript Helena Teede: input into manuscript	No No

I have not renumbered sections of submitted or published papers in order to generate a consistent presentation within the thesis.

Student name: Rebecca Goldstein

Student signature: **Date:** 19/12/2020

I hereby certify that the above declaration correctly reflects the nature and extent of the student's and co-authors' contributions to this work. In instances where I am not the responsible author I have consulted with the responsible author to agree on the respective contributions of the authors.

Main Supervisor name: Professor Helena Teede

Main Supervisor signature: **Date:** 3/12/2020

Thesis by publication and PhD journey

Monash University doctoral candidates are encouraged to submit a thesis by publication including papers that have been prepared or accepted for publication. These papers may include more than one author and can be inserted into the thesis in their published format. The thesis must reflect a sustained and cohesive theme, and introductions framing and linking the chapters and manuscripts can be included.

I obtained my medical degree with honours in 2004 and was admitted to the Fellowship of the Royal Australasian College of Physicians (FRACP) in 2012 as an adult endocrinologist. During my specialty training I was interested in medical research and had a research position at Monash Centre for Health Research and Implementation (MCHRI) in a project on polycystic ovarian syndrome, while I was on maternity leave in 2010. This confirmed my interest in research and my desire to combine research with clinical work in diabetes and endocrinology. In 2014 I pursued a PhD to broaden my research knowledge and gain new skills in the field of Women's Health Research, while continuing my clinical work.

During my candidature, I took maternity leave in 2015 and in 2017. In 2018, my eldest child, Gideon, aged eight, was diagnosed with an aggressive brain tumour. Words cannot describe this heartbreak. Gideon's treatment involved surgery, radiotherapy and targeted chemotherapy treatment. During his treatment, our family were privileged to spend extraordinary quality time with him. In May 2019, almost 12 months after diagnosis, at age nine, Gideon died.

Returning to research in 2019 was a distraction and a comfort. My interest in research was still strong and I have been committed to completing my PhD within the required timeline. The support from my supervisors has made this possible.

This thesis demonstrates the progression of my knowledge and skill set through the development of widely cited systematic reviews on gestational weight gain and the development, implementation and evaluation of The Healthy Lifestyle in Pregnancy Project (HiPP). Throughout my candidature I have advanced as a well-rounded researcher gaining knowledge in women's health in quantitative and qualitative research. I have developed new skills in public health research, biostatistics, epidemiology, project management, collaboration-building with international researchers, data extraction for systematic reviews, evaluation of a medical service, questionnaire design and implementation, qualitative design and interviewing. This has been achieved through formal coursework in Biostatistics, Epidemiology and Public Health, and Qualitative Research; short courses in Leadership; and mentoring by my multidisciplinary team of supervisors.

I have produced work that is highly cited and recognised to have clinical impact, and have been the recipient of three distinguished awards during my PhD: Best Higher Research Degree paper from the School of Public Health and Preventive Medicine, The Henry Burger Prize for Clinical Research from Monash Health, and The Bryan Hudson Clinical Endocrinology Award from the Endocrine Society of Australia.

My advancement is demonstrated within the publications I have produced throughout my PhD candidature. My thesis includes five chapters and eight manuscripts exploring obesity, gestational weight gain and healthy lifestyle in pregnancy (six published and two submitted under consideration).

Excess gestational weight gain, maternal and infant complications and interventions

I began my PhD by performing a comprehensive literature review on gestational weight gain and obesity in pregnancy and the current lifestyle interventions available. This formed one published peer-reviewed publication.

The clinical relevance of the Institute of Medicine guidelines for gestational weight gain

My role in this project involved a literature review to identify the research gap, co-designing the project and performing the systematic review search, study selection, data extraction, data analysis and manuscript preparation and submission. Where additional data analysis was required, I contacted 31 international authors, requesting data reanalysis. I developed project management skills, establishing collaborations with 12 of these authors, and liaised with the legal department to create legal agreements between the parties. The review progress with the Journal of the American Medical Association (JAMA) was complex and demanding, requiring additional data analysis. This chapter formed two well-cited, peer-reviewed publications.

Develop, implement and evaluate the Healthy Pregnancy Service to improve maternal and infant outcomes

My role in this project involved

- Co-design of the study, submission of all ethics applications
- Co-ordination with midwifery services (allocation of women to Healthy Pregnancy Service, appointment scheduling, provision of scales to clinic rooms, access to online Birthing Outcomes System (BOS) to capture outcomes, regular contact to ensure data collection), and provision of a workshop for clinical staff at Healthy Pregnancy Clinic (April 2016) to outline goals of service
- Developing and distributing of two questionnaires for women attending clinic
- Developing an interview schedule and conducting interviews of patients and staff
- Data analysis and manuscript preparation

This project has formed three peer-reviewed publications.

Risk perceptions, health beliefs and satisfaction with diagnosis in women with gestational diabetes (GDM)

In this project I investigated satisfaction with diagnosis, risk perception and health beliefs to improve understanding of barriers and enablers of lifestyle change to inform optimisation of treatment of GDM. These findings around risk perception and health beliefs in a high-risk group informed the planning of questionnaires and the qualitative component in the HiPP. This formed one peer-reviewed publication.

Conclusion and future directions

In this final phase, I have summarised my findings, addressed the strengths and limitations, and reviewed the gaps and future directions. This formed one peer-reviewed publication.

Acknowledgements

Professional

I would like to express my gratitude to Professor Helena Teede, my supervisor and mentor. You have been a wonderful support, providing me with fantastic opportunities to pursue my research. I have appreciated your insight, experience and confidence. Your optimistic attitude and ability to see the end-goal throughout my PhD has been very reassuring.

I express my gratitude to my co-supervisors Associate Professor Jacqueline Boyle and Dr Cheryce Harrison, for their expertise, guidance and support.

All three of my supervisors have allowed me to learn independently, while guiding me in the right direction when required. I sincerely appreciate the support my supervisors have provided me during Gideon's illness and beyond.

I am grateful to Sanjeeva Ranasinha and Dr Marie Misso for their contribution to my systematic review. Thank you to the staff and participants at Dandenong Women's Health for their role in the Healthy Lifestyle in Pregnancy Project.

Special thanks to my PhD colleagues and friends Sally, Soulmaz, Negar, Mahnaz, Adina and Julie for their advice and friendship.

This research was supported by an Australian Government Research Training Program (RTP) Scholarship and a Graduate Research Completion Award.

Personal

I am very grateful to my family for their support over the course of my PhD.

My husband Leigh has played an integral role, and provided wonderful support for me and for our children. Your partnership and patience are exemplary.

I am grateful to my parents, Deidre and Jacob, and my sister Elissa for your intellectual and emotional support, and to my in-laws Felicia and Len for your ongoing encouragement. I appreciate your important role in caring for our children.

Last but not least, thank you to my wonderful children, Gideon, Naava and Isaac. I have been privileged to be your mother and you have brought me so much joy. I look forward to welcoming another child into our family shortly.

Dedications

This thesis is dedicated to my beautiful and loving son Gideon.

Gideon was a gorgeous, funny and gentle boy, devoted to his siblings and family. He loved going to school, loved all things Cookie Monster-related, and entertained everyone with his quirky sense of humour and fantastic memory. We miss him deeply.

Career disruptions and relative to opportunity consideration

January 2015 – January 2016: maternity leave

September 2017 – May 2018: maternity leave

May 2018 – August 2019: carer's leave for Gideon

List of abbreviations, terms and conditions

BMI: Body mass index

FRACP: Fellow of the Royal Australasian College of Physicians

GDM: Gestational Diabetes Mellitus

GWG: Gestational Weight Gain

HiPP: Healthy Lifestyle in Pregnancy Project

IADPSG: International Association of the Diabetes and Pregnancy Study Groups

IOM: Institute of Medicine

IPD: Individual patient data

LGA: Large for gestational age

MCHRI: Monash Centre for Health Research and Implementation

NICU: Neonatal intensive care

OGTT: Oral glucose tolerance test

RCT: Randomised controlled trial

SGA: Small for gestational age

SR: Systematic review

T2DM: Type 2 diabetes

WHO: World Health Organisation

List of conference presentations

Listed below are the candidate's conference presentations and posters regarding research included in this thesis. The presenting author's name is underlined.

Oral presentations

1. **Rebecca Goldstein**, Sally Abell, Marie Misso, Sanjeeva Ranasinha, Jacqueline Boyle, Mary Helen Black, Nan Li, Gang Hu, Francesco Corrado, Line Rode, Young Ju Kim, Margaretha Haugen, Won O Song, Min Hyoung Kim, Annick Bogaerts, Roland Devlieger, Judith H Chung, Helena Teede.
   Gestational weight gain outside Institute of Medicine guidelines: Systematic review and meta-analysis of maternal and infant outcomes in over one million women.

   Different aspects of this work were presented at:

   - ***Endocrine Society of Australia*** *Annual Scientific Meeting, Gold Coast, Australia, 2016*
   - ***Monash Health Translational Precinct (MHTP)*** Research *Week, Victoria, Australia, 2016*
   - ***US ENDO****, Orlando, United* States *2017*
   - ***MHTP*** *Research Week,* Victoria*, Australia, 2017 selected to present in prize session for best of MHTP Research 2016-2017*

2. **Rebecca Goldstein**, Jacqueline Boyle, Cheryce Harrison, Helena Teede.
   A pragmatic lifestyle implemented into antenatal care to optimise gestational weight gain for women with obesity: The Healthy Lifestyle in Pregnancy Project (HiPP).

   Different aspects of this work were presented at:

   - ***Austral-Asia Obesity Research Update*** *Conference, Australia, 2020*
   - ***Endocrine Society of Australia*** *Annual Scientific Meeting, Australia 2020,*
     (Joint recipient of the Bryan Hudson Clinical Endocrinology Award)
   - ***Health in Preconception Pregnancy and Postpartum (HiPPP) Early and Mid-Career Researcher Collective (EMR-C)*** *Conference, 2020*

Poster presentations

1. **Rebecca Goldstein**, Sally Abell, Marie Misso, Sanjeeva Ranasinha, Jacqueline Boyle, Mary Helen Black, Nan Li, Gang Hu, Francesco Corrado, Line Rode, Young Ju Kim, Margaretha Haugen, Won O Song, Min Hyoung Kim, Annick Bogaerts, Roland Devlieger, Judith H Chung, Helena Teede.
   Gestational weight gain outside Institute of Medicine guidelines: Systematic review and meta-analysis of maternal and infant outcomes in over one million women: Ethnic variation and subgroup analysis.

   Different aspects of this work were presented at:

   - ***MHTP*** *Research Week, Victoria, Australia, 2016*
   - ***US ENDO****, Orlando, United States 2017*

2. **Cheryce Harrison**, Rebecca Goldstein, Jaqueline Boyle, Anju Joham, Helena J Teede
   Implementation of a collaborative model of antenatal care to prevent excess gestational weight gain in obese pregnancies.

   This was presented at:

   - ***MHTP*** *Research Week, Victoria, Australia, 2016*

List of awards and prizes

Listed below are awards and scholarships that I have received relevant to the period of candidature.

Year	Award / Prize
2016	**Endocrine Society of Australia Travel Grant** to attend 2016 Annual Scientific Meeting
2017	**Monash University Postgraduate Travel Award** to attend US Endo 2017
2017	**Endocrine Society Outstanding Abstract Award** for Oral Presentation at US Endo 2017
2017	**Endocrine Society of Australia / Australian Women in Endocrinology – Novo Nordisk Travel Award** to attend US Endo 2017
2017	**Henry Burger Prize for Clinical Research** for the best published clinical research by a member of the Senior Medical Staff Association of Monash Health
2018	**Best Higher Research Degree paper** **School of Public Health and Preventive Medicine**, Monash University
2020	**Joint recipient of the Bryan Hudson Clinical Endocrinology Award Session** (oral) Endocrine Society of Australia Annual Scientific Meeting

Scholarships and funding

Listed below are scholarships and funding that I have received relevant to the period of candidature.

Year	Award / Prize
2014	**Research Training Program Scholarship** Monash University
2020	**Graduate Research Completion Award** Monash University

Coursework and short courses

Listed below are coursework, short courses, training and professional development that I have completed relevant to the period of candidature.

Year	Coursework/training
2014	**Master of Public Health, Introduction to Epidemiology MPH 5040** Monash University (High distinction)
2014	**Master of Public Health, Introduction to Biostatistics MPH 5041** Monash University (Credit)
2014	**Introduction to Intellectual Property** Short course, Monash University
2014	**Ethics and Good Research Practice** Short course, Monash University
2014	**Library Focus Series** (literature searching and review; introduction – EndNote; effective reading and note-taking; mind maps to improve writing), Monash University
2016	**Communications Training Course** Monash Centre for Health Research and Implementation, Monash University
2016	**Ethics and Good Research Practice** Short course, Monash University
2016	**Qualitative Research Methods for Public Health** Short Course, Monash University
2020	**Women in Leadership Program** Monash Centre for Health Research and Implementation, Monash University and Monash Partners
2020	**Monash Nursing and Health Science Focus Series: Writing an Effective Literature Review**, Monash University

Media

June 2017 Interview on Radio National *Health Report*, Weight gain in pregnancy

Statement of PhD aims

Overall aims

The overarching aim of my PhD is to explore gestational weight gain and effects on adverse maternal and infant health outcomes, with development and implementation of strategies to achieve healthy pregnancies in these women.

Specific aims

Chapter 1. Excess gestational weight gain, maternal and infant complications and interventions

To conduct a review of the associations of excess gestational weight gain with maternal and infant complications and the effect of lifestyle interventions to limit gestational weight gain.

Chapter 2. The clinical relevance of the Institute of Medicine guidelines for gestational weight gain

To perform a systematic review and meta-analysis of the 2009 Institute of Medicine guidelines for gestational weight gain to understand the maternal and neonatal risks for women with weight gain below and above recommendations.

Chapter 3. Develop, implement and evaluate the Healthy Lifestyle in Pregnancy Project (HiPP) to limit GWG and improve maternal and infant outcomes

To evaluate the Healthy Pregnancy Service at Monash Health, developed for women who are obese at the onset of pregnancy to limit GWG and improve maternal and infant outcomes.

Evaluation will be in three forms:

1. Quantitative: assessment of gestational weight gain, maternal and infant outcomes
2. Qualitative: assessment of health professionals' experiences
3. Mixed-methods: an investigation of pregnant women's experiences

Chapter 4. Risk perceptions, health beliefs and satisfaction with diagnosis in women with gestational diabetes (GDM)

To assess the risk perceptions, health beliefs and satisfaction with diagnosis process in women with gestational diabetes (GDM).

Chapter 5. Conclusion and future directions

To address the key findings, implications and conclusions of this research project.

Chapter 1. Excess gestational weight gain, maternal and infant complications and interventions

1.1 Introduction

In this phase, the goal was to summarise the existing literature on the prevalence, consequences and interventions for excess GWG. This enabled me to identify literature gaps that would inform chapter two (systematic review) and chapter three (lifestyle intervention) components of my PhD.

My aim was to address the key questions in a narrative review:

1. What are the adverse maternal and infant health outcomes associated with excess GWG?
2. What are the different guidelines currently in use for recommended GWG?
3. What effective lifestyle interventions are available for the prevention of excess GWG?

The main findings are summarised below:

1. Adverse health outcomes of excess maternal GWG: observational data

Excess GWG drives some well-recognised short-term adverse maternal outcomes reported in population-based cohort studies, including pre-term birth (2, 5) and caesarean section (2, 5, 9-12). Other outcomes are more debated, including GDM (13, 14) and gestational hypertension/pre-eclampsia (11, 12). Short-term infant outcomes include increased birth weight (2, 5, 11, 12, 15), LGA and reduced risk for SGA (2, 5, 9, 10, 15).

In the long term, excess GWG increases maternal postpartum weight retention at six (10), 12 months (9) and 18 months (10) and predicts long-term obesity (1, 16), which in turn indirectly predicts diabetes, heart disease (17) and chronic disease (1). Childhood overweight/obesity is linked strongly to excess GWG in observational studies (9, 18). New studies are emerging that describe the association with increased maternal GWG and adverse adolescent metabolic profile (19, 20).

2. Guidelines for optimal GWG: observational data

Healthy GWG is not equal across the BMI spectrum. All guidelines allow greater GWG in women who are underweight at the onset of pregnancy. Underweight women can have high GWG without the same consequences of adverse maternal and infant outcomes (10), hence their weight gain allowance is more generous. Most guidelines recommend lower weight gain for overweight and obese women. These women are more likely to exceed recommended weight gain, even though their mean weight gain during pregnancy is less than normal weight women (9, 13, 21).

We have summarised and compared four guidelines: from the US (Institute of Medicine, 2009 (2)), Sweden (Cedergren, 2007 (22)), Germany (Beyerlein, 2009 (23)) and Singapore (Ee, 2014 (24)). Whilst IOM recommendations are most commonly used worldwide, a recent study has shown significant variation in practice internationally in terms of policies on GWG (25).

Table 1. 2009 IOM recommendations for gestational weight gain during pregnancy

	Total weight gain		**Rates of weight gain in 2nd and 3rd trimester**	
Prepregnancy BMI (kg/m²)	Range in kg	Range in lb	Mean (range) in kg/week	Mean (range) in lbs/week
Underweight (<18.5)	12.5-18	28-40	0.51 (0.44-0.58)	1 (1.0-1.3)
Normal weight (18.5-24.9)	11.5-16	25-35	0.42 (0.35-0.50)	1 (0.8-1.0)
Overweight (25.0-24.9)	7-11.5	15-25	0.28 (0.23-0.33)	0.6 (0.5-0.7)
Obese (≥ 30)	5-9	11-20	0.22 (0.17-0.27)	0.5 (0.4-0.6)

The IOM guidelines have been criticised for their lack of global utility, given that they are based on mostly observational studies from developed Western countries and based on an original data set from the 1980s when obesity was less prevalent. To clearly define healthy GWG, the 2009 IOM guidelines need to be validated in the current setting of higher maternal BMIs and greater rates of GWG. Systematic review, meta-analysis and further research is needed addressing adverse outcomes across diverse multi-ethnic populations.

3. Lifestyle interventions in obesity and prevention of excess GWG

We summarise the major systematic reviews and intervention studies. Despite clear health needs and evidence for efficacy of lifestyle interventions in pregnancy, a major gap persists with inadequate translation of healthy lifestyle change integrated into routine preconception and antenatal care.

1.2 Excess gestational weight gain in pregnancy and the role of lifestyle intervention

Goldstein R, Teede H, Thangaratinam S, Boyle J.

Excess gestational weight gain in pregnancy and the role of lifestyle intervention

Semin Reprod Med. 2016 Mar;34(2):e14-21. doi: 10.1055/s-0036-1583531. Epub 2016 May 24.

Excess Gestational Weight Gain in Pregnancy and the Role of Lifestyle Intervention

Rebecca Goldstein, MBBS (Hons), FRACP[1,2] Helena Teede, MBBS, FRACP, PhD[1,2]
Shakila Thangaratinam, MBBS, MRCOG, PhD[3] Jacqueline Boyle, MBBS, FRANZCOG, MPH, PhD[1,4]

[1] Monash Centre for Health Research and Implementation, School of Public Health and Preventive Medicine, Monash University, Victoria, Australia
[2] Diabetes and Endocrinology Units, Monash Health, Monash Medical Centre, Clayton, Victoria, Australia
[3] Women's Health Research Unit, Barts and the London School of Medicine and Dentistry, Queen Mary University of London, London, United Kingdom
[4] Obstetrics and Gynaecology Unit, Monash Health, Clayton, Victoria, Australia

Address for correspondence Helena Teede, MBBS, FRACP, PhD, Monash Centre for Health Research and Implementation, School of Public Health and Preventive Medicine, Monash University, Diabetes and Endocrinology Units, Monash Health, Monash Medical Centre Clayton, Melbourne Victoria 3168, Australia (e-mail: helena.teede@monash.edu).

Semin Reprod Med 2016;34:e14–e21.

Abstract

With increasingly adverse lifestyles, young women in many countries have rapid weight gain and rising obesity. In keeping with this, most pregnant women exceed recommended gestational weight gain (GWG) and then retain weight postpartum. The consequences of excess GWG include maternal risks during pregnancy, neonatal risks and maternal obesity and chronic disease longer term, presenting a significant public health and economic burden worldwide. This article discusses the adverse maternal and infant risks with excess GWG apparent from observational studies, summarizes the existing guidelines for optimal GWG and highlights the need for further research to identify optimal GWG recommendations across the different ethnicities and weight ranges.

We also review the evidence for lifestyle interventions in pregnancy to prevent excess GWG and highlighting the work underway to integrate large scale meta-analyses of individual patient data from lifestyle intervention studies to inform clinical practice beyond current observational data. Finally, we address the need to implement lifestyle interventions into routine pregnancy care to improve short and long term maternal health outcomes.

Keywords
- gestational weight gain (GWG)
- outcomes
- intervention
- body mass index (BMI)

Obesity secondary to adverse lifestyle presents a major public health and economic burden worldwide. Established obesity requires intensive, multidisciplinary and costly treatment. Once obesity is established, lifestyle induced weight loss is largely unsustainable due to physiological adaptation which drives weight regain.[1,2] In contrast, prevention of weight gain is feasible with minor lifestyle changes[3,4] and small energy balance adjustments (~220kJ/day),[3] conveying long term health benefits. In this context, the World Health Organization (WHO) global strategy for the prevention of non-communicable diseases notes obesity as a preventable condition and recommends to aim to increase physical activity and improve diet[5] to prevent obesity. This is therefore now a high priority internationally.[6]

The health implications of weight gain are major and the risks increase with each kg gained across all weight categories, making prevention a priority for all women. Diabetes risk increases above BMI of 22 kg/m^2 with 18% affected in normal weight, 35% in overweight and 75% in obese women.[7] Cardiovascular disease is the number one cause of mortality from

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non-communicable disease in women and increases by 3% for each kilo gained.[8] As 55% of deaths are lifestyle or weight related, the imperative for effective obesity prevention interventions is critical.[9]

Pregnancy is a key driver of weight gain, with most women in developed countries exceeding recommended gestational weight gain (GWG) with a mean 2–5 kg retained per pregnancy.[10–13] Excess GWG is directly related to long-term obesity across all weight categories.[14] Longitudinal data shows a 300% increase in obesity risk long term if GWG exceeds guidelines.[12] Excess GWG thus drives long term obesity and chronic disease.[12] Pregnancy therefore offers significant opportunities for obesity prevention[6] and reproductive aged women are now targeted as a high risk group with recommendations to limit GWG and encourage postpartum weight loss.[15]

In additional to driving maternal obesity, excess GWG also worsens pregnancy complications for both mothers and babies.[16] GWG is an independent predictor of large for gestational age babies and related complications.[17] The Institute of Medicine (IOM) in the USA has made recommendations for optimal GWG[18] based on maternal BMI, although the observational cohorts underpinning these recommendations were from the USA in 1980 with limited obesity and little ethnic diversity.

With regards to lifestyle interventions, leading researchers in the field and the WHO have recognized that the environmental and societal factors driving obesity must be addressed for effective widespread obesity prevention.[19,20] However environmental and societal changes have proven slow to change with WHO noting that obesity is one of today's most blatantly visible – yet most neglected – public health problems. Ultimately however, individual behavior change, ideally enabled by societal and environmental change is needed to prevent and manage obesity. The evidence on individually targeted lifestyle initiatives is reviewed here, while acknowledging the need for concomitant broader societal and environmental approaches to support individual lifestyle change.[20]

There is currently no literature on healthy lifestyle interventions preconception, despite education opportunities in this life phase. Adopting healthy lifestyle interventions in pregnancy with positive changes to dietary intake and physical activity prevents excess GWG gain and may reduce pregnancy complications based on systematic review and meta-analysis.[21] They do not impact on birth weight, or result in safety concerns for the fetus.[21] Factors associated with intervention success include focusing on diet or combined interventions, using behavioral strategies and using technology to support delivery.[21–24] However, despite the clear health needs and evidence for the efficacy of lifestyle interventions in pregnancy, a major gap persists with inadequate translation of healthy lifestyle change integrated into routine preconception and antenatal care.

Barriers to incorporating a focus on healthy lifestyle behaviors into pregnancy care include women's limited knowledge and awareness of healthy GWG and adverse effects of excess GWG on long term health; inadequate health professional skills, support and training[25]; sociocultural challenges for health professionals and women, limited accessibility of evidence based programs and resources, inadequate staff time and health system challenges.[26] Enablers include the "teachable moment" with pregnant women more motivated to accept healthy behaviors in pregnancy[26–29] for the health of their child, and health system engagement with frequent antenatal visits. However, there is inadequate existing implementation research addressing these barriers and leveraging off these enablers.

Currently, extensive international individual patient data meta-analysis of lifestyle interventions in pregnancy is underway and this data will enable us to answer key questions on the efficacy of lifestyle interventions, including diet, physical activity and mixed interventions in pregnancy for prevention of GWG.[30] It will also allow exploration of lifestyle intervention impact on maternal and neonatal outcomes, and their relative efficacy across the BMI range and different ethnicities.

Here, we consider opportunities for education on diet and lifestyle preconception. We then review the relevant literature on the adverse health outcomes of excess maternal GWG and recommendations for optimal GWG and controversies around existing Institute of Medicine Guidelines for GWG. We also review the literature on lifestyle interventions in pregnancy and outline the pending large scale international individual patient data meta-analysis in this area. We then close with a discussion around next steps toward implementation of healthy lifestyle into routine pregnancy care to prevent excess gestational weight gain.

Preconception Intervention Opportunities to Prevent Weight Gain

Most women do not engage in maternity care until late in their first trimester. Therefore, pre-conception offers an opportune time for screening for risk factors that may impact on fertility, pregnancy and the future child. There is no evidence from randomized controlled trials (RCT) to support specific interventions or specific models of care pre-conception to improve pregnancy outcomes in overweight or obese women.[31] However, the preconception period provides an opportunity to assess for and manage weight associated maternal chronic conditions including diabetes, hypertension, sleep apnoea and polycystic ovary syndrome.[32–34] It is also an ideal time to discuss and offer an individualized diet and physical activity as weight loss pre-conception will improve fertility and pregnancy outcomes in overweight or obese women. Diet and physical activity pre-conception may also improve GWG; a community based RCT of a 6 group session intervention on physical activity, diet, stress and health behaviors pre-conception and inter-conception showed changes in diet, self-efficacy and reported physical activity preconception.[35] They then followed up women and assessed them across BMI categories; those who were in the intervention group had lower BMI at 12 month follow up and a trend to lower pregnancy GWG after adjustment for pre-pregnancy BMI.[36] Increased levels of physical activity

pre-conception are also associated with trends in decreased GWG.[37] Preconception lifestyle interventions also have the potential to limit first trimester GWG. Until further evidence emerges on the role of preconception interventions for limiting excess GWG, as per National Centre for Clinical Excellence guidelines, addressing chronic conditions and lifestyle factors related to weight in overweight and obese women should be considered.[38]

Adverse Health Outcomes of Excess Maternal GWG: Observational Data

In the US, Europe and Australia, 20–50% of women gain more than the recommended GWG during pregnancy.[39] GWG has major implications in pregnancy, independent of maternal obesity, with every kilo above recommended, linked to 10% increase in adverse outcomes.[16] The combination of excess GWG and obesity is concerning and preventing excess GWG across all BMI categories is imperative.

Excess GWG drives some well-recognized short-term adverse maternal outcomes reported in population-based cohort studies (►**Table 1**), including pre-term birth[13,40] and caesarean section.[13,40–44] Other outcomes are more debated, including gestational diabetes (GDM)[17,45] and gestational hypertension/pre-eclampsia.[42,44] Short-term infant outcomes include increased birth weight,[13,40,42,44,46] LGA and reduced risk for SGA.[13,40,41,43,46]

In the long term, excess GWG increases maternal postpartum weight retention at six,[43] twelve months[41] and eighteen months[43] and predicts long-term obesity,[47,48] which in turn indirectly predicts diabetes, heart disease[49] and chronic disease.[48] Childhood overweight/obesity is also linked strongly to excess GWG on observational studies.[41,50] Recent literature has also described the association of increased maternal GWG and an adverse adolescent metabolic profile.[51,52]

It is difficult to make meaningful comparisons of the severity and frequency of these outcomes across the observational studies in this area due to differing classification of BMI and GWG categories, differing outcome definitions, inconsistent control for confounding factors and variable study methods. Refinement of core outcome sets and standard endpoint definitions for research in this area is needed, along with intervention research linked to long term cohort studies to explore health outcomes for mothers and children.

Recommendations for Optimal GWG: Observational Data

As noted, to create comprehensive guidelines regarding ideal GWG, there should be a consensus on core outcome sets and agreed definitions on core endpoints. Currently, this is lacking and guidelines base recommendations on inconsistently applied and defined outcomes from observational studies. Approaches such as that used by Thangaratinam[21] with a two round Delphi survey of experienced clinicians to rank outcomes for importance in their meta-analysis of interventions in pregnancy is progressing this area and we look forward to clearly defined core outcomes sets in future.

Healthy GWG is not equal across the BMI spectrum. All guidelines allow greater GWG in women who are underweight at the onset of pregnancy. Nohr[43] found that underweight women can have high GWG without the consequences of adverse maternal and infant outcomes, hence their weight gain allowance is more generous. Most guidelines recommend lower weight gain for overweight and obese women, and across ethnicities, these women are more likely to exceed recommended weight gain, even though their mean weight gain during pregnancy is less than normal weight women.[17,41,53]

►**Table 2** summaries the key guidelines. Presently, the IOM 2009[13] guidelines are most commonly used. They are an updated version from the 1990 guidelines, where the 1990 emphasis was on avoiding the consequences of low GWG rather than high GWG, with respect to infant outcomes only. They differ from the 1990 guidelines because they are based on the WHO cut points for maternal BMI categories and include a new narrow range of GWG for obese women. The 2009 guidelines identified maternal and infant outcomes that were based on the Agency for Healthcare research and Quality (AHRQ) systematic review from 2008[40] and commissioned additional analyses. However the 2009 IOM guidelines still derived recommendations from the same original dataset of US based largely Caucasian women in the 1980's when overweight and obesity in pregnancy was relatively uncommon and GWG was more limited. Infant outcomes were SGA, LGA, preterm birth and childhood obesity. Maternal outcomes selected included postpartum weight retention, caesarean section, GDM, gestational hypertension; however, GDM and gestational hypertension were removed from analysis due to lack of sufficient evidence from methodologically

Table 1 Risks of excess GWG

	Short term	Long term
Maternal outcomes	GDM	Post partum weight retention
	Pre-eclampsia/ gestational hypertension	Obesity
	Pre-term birth	
	C section	
Infant outcomes	Increased birth weight	Childhood obesity
	LGA	
	Low risk of SGA	

flawed observational studies. Strengths of IOM are that the severity and the frequency of the outcomes have been considered in building the guidelines, which other guidelines have not done.

Cedergren[16] recommended optimal GWG recommendations based on a large Swedish population-based cohort registry of nearly 300,000 women, almost all of Caucasian origin (►**Table 2**). Interestingly, selection of outcome variables directly related to maternal GWG and BMI was not the purpose of the study. Rather, the aim was to 'estimate weight gain limits that were associated with significantly decreased risk of the most clinically dangerous situations for the mother and the infant'. Analysis included SGA, LGA, preeclampsia and several short-term maternal and infant complications. Recommendations emerging from this work have a narrower limit for GWG than IOM, across all BMI categories. Of note, the outcomes were not weighted for severity and a number are rare, perhaps limiting usefulness. Moreover, weight gain information was only available in <40% of women.

The 1990 IOM and Cedergren recommendations have been directly compared using the New Jersey Pregnancy Risk Assessment Monitoring System (PRAMS) database of over 9000 women.[54] Using the Cedergren guidelines, the incidence of macrosomia and caesarean delivery was lower, however low birth weight, preterm deliveries and neonatal intensive care admissions occurred more frequently. Ideal GWG was assessed to be between both these sets of recommendations.

The IOM guidelines have also been evaluated in large observational datasets. A German study based on more than 170,000 deliveries (►**Table 2**) created a model for joint predicted risks of SGA and LGA in relation to GWG and found much wider optimal GWG ranges across the BMI range.[55] More recently, the Norwegian Mother and Child Cohort

Table 2 Key guidelines for GWG

Author	Rasmussen (IOM)	Cedergren	Beyerlein	Ee
Year	2009	2007	2009	2014
Country of origin	US	Sweden	Germany	Singapore
Guideline development based on	Systematic review, commissioned reports	Population based cohort study	population based cohort study	population based cohort study
Maternal outcomes assessed	Caesarean section	Preeclampsia, eclampsia	N/A	Caesarean section
	Post partum weight retention	Postpartum hemorrhage		Vaginal delivery
		Venous complications		
		Shoulder dystocia		
		Complications of anesthesia		
		Stillbirth after 28 weeks		
Infant outcomes assessed	SGA	SGA	SGA	SGA
	LGA	LGA	LGA	LGA
	Preterm birth	Birth trauma		AGA (appropriate for
	Childhood obesity	Respiratory disorders		Gestational age)
		Bacterial sepsis		
		Haemorrhagic disorders		
		Convulsions		
		perinatal death		
		Apgar score < 7 at 5 minute		
Proposed optimal GWG	**Weight in kg**			
BMI categories (kg/m^2)				
Underweight < 18.5	12.5–18	4 - 10*	8- 25	19.5 (12.9 to 23.9)***
Normal weight 18.5–24.9	11.5–16	2- 10*	2–18	13.7 (7.7 to 18.8)**
Overweight 24.9–29.9	7–11.5	< 9	-7 to 12	7.9 (2.6 to 14.0)**
Obese ≥30	5–9.0	< 6	-15 to 2	1.8 (-5.0 to 7.0)**

* BMI cutoff of 20.

** BMI cutoff of 18.5 to < 23 for normal weight; 23 to <27.5 for overweight; ≥ 27.5 for obese.

***numbers in paraenthesis represent the lower and upper markings of the GWG range for which aggregated risk of composite adverse outcome does not exceed a 5% increase from the lowest aggregated risk.

Study[42] evaluated the risk of several maternal and infant outcomes with a GWG outside of the guidelines in data on more than 50,000 women. There was an increased risk of macrosomia, preeclampsia and emergency caesarean section in the normal weight and overweight groups who exceeded GWG recommendation. Excess GWG across all weight gain groups resulted in postpartum weight retention of >2kg at 18 months.

The IOM guidelines have been criticized for their lack of global utility, given that they are based on mostly observational studies from developed Western countries. Their use of WHO BMI cut points are not specific for Asian women. With this is mind, Ee[56] et al used the WHO BMI cut points for Asian women and created new optimal GWG recommendations in their multiethnic Singapore cohort (►**Table 2**). Of interest, optimal GWG in underweight and obese women was outside the IOM range.

While IOM recommendations currently guide practice in many countries, a recent study has shown significant variation in practice internationally in terms of policies on GWG.[57] To clearly define healthy GWG, the 2009 IOM guidelines need to be validated in the current setting of higher maternal BMI's and greater rates of GWG. Systematic review, meta-analysis and further research is needed addressing adverse outcomes across diverse multi-ethnic populations.

Lifestyle Interventions and the Need for More Research

Prevention of obesity is important for all lifelong. In this context, targeting pregnant women in prevention of weight gain is important as i) there are significant reproductive implications of obesity ii) many women now exceed international GWG recommendations[11,13,58,59] and ~2–5kg are retained per pregnancy[13,60] iii) pregnancy offers a defined life stage for women captured in our existing health system with enablers for lifestyle change iv) healthy lifestyle change in pregnancy improves outcomes v) weight gain during pregnancy contributes significantly to maternal obesity with potential for long term health benefits vi) women influence family lifestyle with maternal lifestyle changes having broader implications for families and communities.

Lifestyle interventions in pregnancy focusing on improving dietary intake and physical activity has been shown in a comprehensive systematic review of 7278 women to prevent excess GWG gain. Overall, there was 1.42 kg less weight gained (95% confidence interval 0.95 to 1.89 kg) and lifestyle intervention reduced preeclampsia (OR 0.39 - 0.74) and shoulder dystocia (OR 0.39), with a trend to reduced GDM (OR 0.78, CI 0.57–1.08).[21] Lifestyle intervention do not appear to impact on birth weight, or have safety concerns.[21] Monitoring maternal weight alone is ineffective, but improves efficacy when used in combination with interventions.[61]

There are many effective lifestyle interventions in pregnancy. The Healthy Lifestyle Program for women (HeLP-her) is one example of an effective intervention.[21] The HeLP-her program is an evidence-based self-management weight gain prevention intervention initially targeting reproductive aged non pregnant women and published in the BMJ.[62] Now trialled across different urban and metropolitan settings and populations, it has demonstrated efficacy in over 1000 women including women in pregnancy.[10,63,64] HeLP-her has significant evidence of efficacy for weight gain prevention and is designed for implementation as a low cost pragmatic simple intervention that leverages off self-management and is integrated into routine antenatal care.[6] It involves simple dietary and activity messages, self-management, behavioral strategies such as goal setting, problem solving, relapse prevention, self-monitoring, phone coaching and SMS reminder messages[65] shown to support small lifestyle behavior changes and effective weight gain prevention.[66,67] Diet messages follow national guidelines and include increased unprocessed grains, fruits and vegetables.[10,21,64] HeLP-her has now been adapted to target limiting excess GWG, promoting postpartum weight loss and preventing type II diabetes in women with a history of GDM. This intervention is being trialled in large scale implementation research across low-mid socioeconomic, multiethnic countries in an internationally funded RCT of 1600 women in resource poor settings.

The UPBEAT study focused solely on obese women ($n = 1555$, mean BMI 36.3kg/m^2), with the primary outcomes of maternal diagnosis of GDM and reduction of LGA. The intervention was relatively intensive with 8, mainly group sessions combining behavioral components, dietary and physical activity advice. GWG and skinfold thickness were lower in the intervention group, although results were modest with 0.55kg (95%CI -1.08 to -0.02) less GWG in the intervention group, and no maternal or neonatal benefits demonstrated.[68,69]

The LIMIT study in Australia again had primary outcomes focused on reduction in neonatal complications, with the primary endpoint being reduction in LGA, rather than prevention of weight gain alone. Here, 2212 overweight and obese women were randomized to standard care with or without an additional lifestyle intervention. The intervention was delivered by a dietitian and was not integrated with routine antenatal care.[70] This study did not show differences in the primary endpoint, but did show a reduction in babies born over 4000 gms.[70] These results are consistent with the majority of the literature in this area, which shows a failure to impact significantly on birth weight.[21]

Overall, antenatal lifestyle interventions, prevent excess GWG and offer important obesity prevention opportunities at a vital life stage, when women are engaged with the health system,[6] yet they do not significantly alter birth weights and appear to have limited impact on neonatal outcomes.

Although systematic reviews had identified beneficial effects of mainly diet based, physical activity based and mixed interventions,[21] findings are limited by the variation in the characteristics of the population, intervention and outcomes. The effects of lifestyle interventions on various groups of women based on BMI category, age, ethnicity, parity and risk status in pregnancy is not known. These questions cannot be answered from published aggregate data, as patient-level information is not available and subgroup effects ('treatment-covariate interactions') are usually not reported in

sufficient detail. However, these gaps in evidence can be addressed by meta-analysis of individual participant data IPD, where the raw patient-level data are obtained and synthesized across trials.

The International Weight Management in Pregnancy (i-WIP) individual patient data (IPD) collaborative network is funded by the UK National Institute for Health Research (NIHR) to assess differential weight management interventions in pregnancy by BMI, age, ethnicity, parity and underlying medical conditions on a) maternal weight and b) composite pregnancy outcome of maternal and fetal complications.[30] The Network also aims to quantify the relationship between the amount of weight gained in pregnancy and the risk of adverse maternal and fetal outcomes for normal weight, overweight and obese women. The i-WIP Network comprises 36 principal investigators from 17 countries, and comprises of obstetricians, physicians, nutritionists, physiotherapists, researchers, dieticians, exercise physiologists, midwives, nurses and consumers involved in the evaluation of diet and physical activity on GWG and other complications in pregnancy.

The findings of the i-WIP initiative will soon enable us to clearly define the efficacy of lifestyle interventions in pregnancy to prevent excess GWG and obesity. It will also provide clarity on maternal (e.g., GDM, preeclampsia) benefits. Remaining clinical and research gaps which should be addressed in the i-WIP work, include the most effective components of lifestyle interventions, optimal delivery modes and a cost benefit analyses.[30] This important information will inform implementation (the next vital step) and scale up of healthy lifestyle interventions to target the broader population of pregnant women outside those in randomized controlled trials.

In considering implementation of lifestyle interventions into routine antenatal care, barriers need to be addressed. Misperceptions around healthy weight among health professionals and women need to be redressed. For example, it is estimated that less than 16% of obese pregnant women identify as obese.[71] Inadequate weight monitoring in routine care and disparities in medically advised GWG targets also needs to be rectified.[72] Only 4% of obstetricians and midwives accurately identified IOM GWG recommendations,[26] only 25–30% suggested weight targets; only 1% base targets on IOM guidelines and ~70% reported inadequate training in lifestyle behavior change methods.[26] In a midwifery survey, provision of lifestyle advice by midwives was limited and interventions to assist women and staff in developing skills to aid this intervention provision were lacking.[73]

Alongside identified barriers, implementation gaps in prior interventions include failure to partner to establish problems, engage stakeholders, address barriers and enablers, use implementation informed study design; expand beyond single institutions, as well as inconsistent designs, poor or unreported recruitment. There has been a lack of focus on normal and overweight women at highest risk of additional weight retention postpartum, failure to use theoretical frameworks, apply evidence based components, integrate into routine antenatal care and to provide implementation resources for health services and for health professionals. Finally there has also been limited postpartum extension[74] and lack of evaluation. Implementation research is now needed to address these barriers and gaps. We need to know how best to address health system and health professional factors including how to engage, train and support health professionals in lifestyle change. Ideally this will include integrating key lifestyle message prompts, weighing reminders and triggers when GWG is exceeded, into routine maternity care workflows, as this approach is known to increase application of clinical guidelines by 20-fold compared with provision of guidelines alone.[75]

Conclusion

Overweight and obesity present a major and neglected public health burden. Reproductive aged women are a recognized high risk target group for weight gain and related complications. Excess GWG is a significant contributor to obesity in women which carries independent increased risks of adverse maternal and infant outcomes, including and not limited to caesarean section, increased birth weight, LGA and long term maternal and childhood obesity. Further research is required to assist in refining and optimizing GWG recommendations across different BMI categories and ethnic groups. Individually targeted antenatal lifestyle interventions effectively limit excess GWG, contributing to prevention of obesity in reproductive aged women. Specific maternal and neonatal pregnancy benefits of these interventions still require clarification. Optimal components of antenatal lifestyle interventions as well as the cost effectiveness of these interventions are currently being researched through an international individual patient data meta-analysis of lifestyle interventions in pregnancy that will guide practice and policy in this area. We then require pragmatic implementation strategies to scale up healthy lifestyle into routine antenatal care.

Ultimately, antenatal interventions need integration with prevention efforts across the life stages including in childhood and adolescence and preconception to prevent maternal weight related pregnancy complications. While ultimately healthy lifestyle is a matter of individual behavior change, individual interventions must extend beyond individual targeted initiatives to address societal and environmental factors and enable children, adolescents and women to have a healthier lifestyle and to prevent obesity and related complications.

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Chapter 2. The clinical relevance of the Institute of Medicine guidelines for gestational weight gain

2.1 Introduction

The narrative review in chapter one identified a gap in the literature – that is, in our diverse, multi-ethnic population, with the increasing prevalence of obesity, what are the maternal and infant risks associated with weight gain outside of the 2009 IOM recommendations?

Clear evidence gaps include the need to systematically (i) analyse contemporary cohorts of women across the entire BMI range, in particular those with higher BMIs, (ii) focus on consequences of both low GWG and the more common excessive GWG, (iii) incorporate maternal and infant outcomes, and (iv) extend beyond US populations to include other ethnicities.

The aim of the review was to assess the association of GWG (specific for each BMI category) and outcomes of SGA, preterm birth, LGA, macrosomia, GDM and caesarean delivery. These outcomes were selected based on previous IOM studies (26) and a Delphi survey of clinicians that was used to rank clinically important outcomes in a meta-analysis of lifestyle interventions to reduce weight gain in pregnancy (8). Studies were included if they presented data examining women by prepregnancy BMI category, stratified by the total gestational weight gain.

My role in this project involved a literature review to identify the research gap with my supervisors, then co-designing the project. I performed the systematic review search, study selection, data extraction, data analysis and manuscript preparation and submission. I led engagement with international authors and where additional data analysis was required, I contacted the 31 international authors, requesting data reanalysis. I developed project management skills, establishing collaborations with 12 of these authors, and liaised with the legal department to create legal agreements between the parties.

The peer review progress with the Journal of the American Medical Association (JAMA) was an excellent learning opportunity – intensive, complex and demanding, and requiring additional data analysis. This paper was also the focus of an editorial.

The association between the guidelines and pregnancy outcomes across ethnicities is uncertain. As such, in the second comprehensive analysis from the systematic review published in JAMA, I evaluated the associations of GWG outside guidelines with maternal and infant outcomes as a proxy for ethnic groups. This reached across the USA, Western Europe and East Asia, with subgroup analyses in Asia. The aim was to explore ethnic differences in maternal prepregnancy BMI, GWG and health outcomes across the regions and to explore the relevance of IOM guidelines across different ethnic groups.

This chapter presents the results of two well-cited peer-review publications: the main systematic review paper and a sub-analysis across continents and ethnicities.

2.2 Association of gestational weight gain with maternal and infant outcomes: A systematic review and meta-analysis

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Association of gestational weight gain with maternal and infant outcomes: A systematic review and meta-analysis

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JAMA | Original Investigation

Association of Gestational Weight Gain With Maternal and Infant Outcomes
A Systematic Review and Meta-analysis

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IMPORTANCE Body mass index (BMI) and gestational weight gain are increasing globally. In 2009, the Institute of Medicine (IOM) provided specific recommendations regarding the ideal gestational weight gain. However, the association between gestational weight gain consistent with theIOM guidelines and pregnancy outcomes is unclear.

OBJECTIVE To perform a systematic review, meta-analysis, and metaregression to evaluate associations between gestational weight gain above or below the IOM guidelines (gain of 12.5-18 kg for underweight women [BMI <18.5]; 11.5-16 kg for normal-weight women [BMI 18.5-24.9]; 7-11 kg for overweight women [BMI 25-29.9]; and 5-9 kg for obese women [BMI ≥30]) and maternal and infant outcomes.

DATA SOURCES AND STUDY SELECTION Search of EMBASE, Evidence-Based Medicine Reviews, MEDLINE, and MEDLINE In-Process between January 1, 1999, and February 7, 2017, for observational studies stratified by prepregnancy BMI category and total gestational weight gain.

DATA EXTRACTION AND SYNTHESIS Data were extracted by 2 independent reviewers. Odds ratios (ORs) and absolute risk differences (ARDs) per live birth were calculated using a random-effects model based on a subset of studies with available data.

MAIN OUTCOMES AND MEASURES Primary outcomes were small for gestational age (SGA), preterm birth, and large for gestational age (LGA). Secondary outcomes were macrosomia, cesarean delivery, and gestational diabetes mellitus.

RESULTS Of 5354 identified studies, 23 (n = 1 309 136 women) met inclusion criteria. Gestational weight gain was below or above guidelines in 23% and 47% of pregnancies, respectively. Gestational weight gain below the recommendations was associated with higher risk of SGA (OR, 1.53 [95% CI, 1.44-1.64]; ARD, 5% [95% CI, 4%-6%]) and preterm birth (OR, 1.70 [1.32-2.20]; ARD, 5% [3%-8%]) and lower risk of LGA (OR, 0.59 [0.55-0.64]; ARD, −2% [−10% to −6%]) and macrosomia (OR, 0.60 [0.52-0.68]; ARD, −2% [−3% to −1%]); cesarean delivery showed no significant difference (OR, 0.98 [0.96-1.02]; ARD, 0% [−2% to 1%]). Gestational weight gain above the recommendations was associated with lower risk of SGA (OR, 0.66 [0.63-0.69]; ARD, −3%; [−4% to −2%]) and preterm birth (OR, 0.77 [0.69-0.86]; ARD, −2% [−2% to −1%]) and higher risk of LGA (OR, 1.85 [1.76-1.95]; ARD, 4% [2%-5%]), macrosomia (OR, 1.95 [1.79-2.11]; ARD, 6% [4%-9%]), and cesarean delivery (OR, 1.30 [1.25-1.35]; ARD, 4% [3%-6%]). Gestational diabetes mellitus could not be evaluated because of the nature of available data.

CONCLUSIONS AND RELEVANCE In this systematic review and meta-analysis of more than 1 million pregnant women, 47% had gestational weight gain greater than IOM recommendations and 23% had gestational weight gain less than IOM recommendations. Gestational weight gain greater than or less than guideline recommendations, compared with weight gain within recommended levels, was associated with higher risk of adverse maternal and infant outcomes.

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Editorial page 1

Supplemental content

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Excessive and insufficient gestational weight gain have been associated with adverse pregnancy outcomes, including small for gestational age (SGA), large for gestational age (LGA), macrosomia, cesarean delivery, gestational diabetes mellitus (GDM), preeclampsia, postpartum weight retention, and offspring obesity.[1-4] The Institute of Medicine (IOM; now known as the National Academy of Medicine) recommendations regarding gestational weight gain were developed in 1990 to guide clinical practice.[5] These aimed to reduce the incidence of low-birth-weight babies and were based on a 1980 National Natality Survey of a largely white population. The updated IOM guidelines in 2009[6] incorporated World Health Organization (WHO) categories of maternal body mass index (BMI; calculated as weight in kilograms divided by height in meters squared; BMI for underweight, <18.5; normal weight, 18.5-24.9; overweight, 25-29.9; and obese, ≥30)[7] and recommended less gestational weight gain for obese women (**Table 1**). The 2009 guidelines identified maternal and infant relationships with gestational weight gain but were based on lower general population BMI with limited ethnic diversity. The 2009 IOM guidelines are endorsed by the American College of Obstetricians and Gynecologists, although they are not universally implemented.[8]

The prevalence of obesity and excess gestational weight gain are increasing. The US female obesity prevalence was 40% in 2013-2014.[9] More than 50% of obese pregnant women gained gestational weight greater than the IOM gestational weight gain recommendations in a US study that collected data from 2002 through 2008.[10]

The purpose of this review and meta-analysis was to compare gestational weight gain with IOM guidelines from diverse international cohorts and to evaluate associations between gestational weight gain above and below guidelines with maternal and infant outcomes.

Key Points

Question What is the association between gestational weight gain above or below the Institute of Medicine guidelines and maternal and infant outcomes?

Findings In this systematic review and meta-analysis of 1 309 136 pregnancies, gestational weight gain below recommendations (in 23% of women) was associated with higher risk of small for gestational age (odds ratio [OR], 1.53) and preterm birth (OR, 1.70) and lower risk of large for gestational age (OR, 0.59) and macrosomia (OR, 0.60). Gestational weight gain above recommendations (47%) was associated with lower risk of small for gestational age (OR, 0.66) and preterm birth (OR, 0.77) and higher risk of large for gestational age (OR, 1.85), macrosomia (OR, 1.95), and cesarean delivery (OR, 1.30).

Meaning Gestational weight gain below or above the Institute of Medicine guidelines was associated with higher risk of some adverse maternal and infant outcomes.

Methods

This systematic review, meta-analysis, and metaregression was prospectively registered with PROSPERO International Prospective Register of Systematic Reviews (PROSPERO identifier CRD42015023325).

Search Strategy

A systematic search string of relevant terms was developed (eAppendix 1 in the Supplement). Searched databases in Ovid included EMBASE, all Evidence-Based Medicine Reviews, MEDLINE, and MEDLINE In-Process from January 1, 1999, to January 28, 2016 (**Figure 1**). The search was limited to articles from 1999 onward to represent more current populations. The search was later updated to February 7, 2017. Of 7 newly identified studies, 4 were included in the analyses. Three studies were excluded because the data were not in the required format, and there was insufficient time to obtain data from the authors. Bibliographies of included studies were reviewed to identify additional studies. Details of the search strategy and data extraction are shown in eAppendix 2 in the Supplement.

Study Eligibility Criteria

Observational studies published in English and assessing singleton pregnancies in women aged 18 years or older were included. Study sample sizes larger than 500 women were required to identify outcomes present across the BMI categories. We postulated that small studies would have insufficient sample size to detect outcomes within each BMI group. Studies were included if they presented data examining women by prepregnancy BMI category, stratified by the total gestational weight gain. Studies that categorized by mean weight gain per week were excluded. Only studies presenting odds ratios (ORs) stratified by maternal BMI and gestational weight gain were included. Studies that simultaneously adjusted for categories of BMI and gestational weight gain to estimate the independent associations of weight change with outcomes were excluded because the aim of this review was to assess the association of gestational weight gain (specific for each BMI category) and outcomes.

Studies meeting these criteria used different BMI categories (eg, Metropolitan Life Insurance Tables, WHO classifications, or Chinese classifications[11] [BMI for underweight, <18.5; normal weight, 18.5-23.9; overweight, 24-28; and obese, ≥28]) and gestational weight gain categories (eg, 1990 IOM, 2009

Table 1. Recommendations for Gestational Weight Gain During Pregnancy[a]

	Prepregnancy Weight			
Recommendation	Underweight	Normal Weight	Overweight	Obese
BMI	<18.5	18.5-24.9	25-29.9	≥30
Total weight gain range, kg	12.5-18	11.5-16	7-11.5	5-9
Total weight gain range, lbs	28-40	25-35	15-25	11-20

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared).

[a] Adapted from 2009 Institute of Medicine guidelines.[6]

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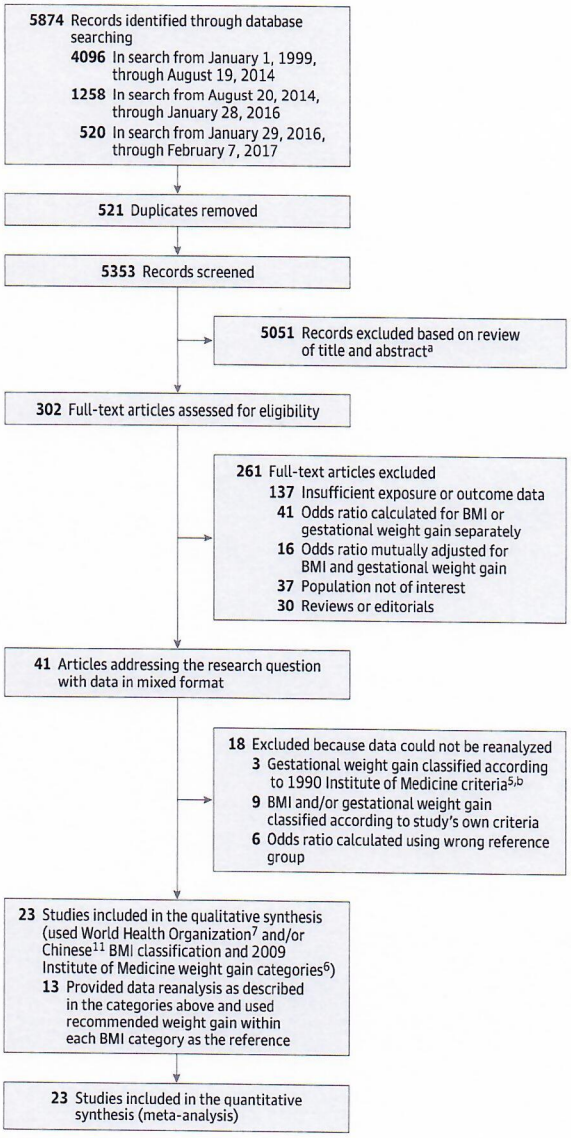
Figure 1. Flow Diagram of Study Selection Process



[a] Exact breakdown for exclusion not documented.

[b] The Institute of Medicine 1990 guidelines differ from the 2009 guidelines. In the 1990 guidelines, the recommended weight gain range was 12.5 to 18 kg for women with a body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) less than 19.8; 11.5 to 16 kg for women with a BMI of 19.8 to 26.0; 7 to 11.5 kg for women with a BMI between 26.0 and 29.0; and at least 6.8 kg for women with a BMI higher than 29.0.

IOM, population-specific, or study-specific categories) to classify participants. Additionally, some studies used a reference of normal gestational weight gain within each BMI group, whereas others used a reference of normal-weight women with normal weight gain.

In this review, BMI was defined by WHO categories and/or Chinese BMI categories. Gestational weight gain was defined by 2009 IOM criteria; thus, authors of identified studies were contacted to reanalyze data using these categories. The ORs were calculated using recommended gestational weight gain within each BMI category as the reference.

Gestational weight gain was defined as the difference between the final weight and the prepregnancy weight and was classified as below, within, or above the 2009 IOM guidelines. The prepregnancy weight was either self-reported (which correlates well with measured weight[12,13]) or measured at first antenatal visits. Final pregnancy weight was measured at the last antenatal visit or the time of delivery or was self-reported within 1 year of delivery.

Primary outcomes were the following: (1) SGA, indicated by birth weight less than the 10th percentile for gestational age; (2) preterm birth, indicated by spontaneous birth before 37 weeks' gestation; and (3) LGA, indicated by birth weight greater than the 90th percentile for gestational age. Secondary outcomes were the following: (1) macrosomia, indicated by birth weight greater than 4000 g; (2) cesarean delivery; and (3) GDM. Outcomes were selected based on the original IOM studies,[6] and end points were determined on a 2-round Delphi survey of experienced clinicians that was used to rank clinically important outcomes in a meta-analysis of lifestyle interventions to reduce weight gain in pregnancy.[14]

Risk of Bias Appraisal

Two authors assessed risk of bias (R.F.G. and S.K.A.). Discrepancies were resolved by consensus in discussion with a third reviewer (M.M.). Methodological quality of included studies was assessed using the Monash Centre for Health Research and Implementation evidence synthesis appraisal assessment tool.[15,16] Individual quality items were assessed using a descriptive approach including exposure and outcome measures, reporting bias, confounding, and conflict of interest. Each study was classified as low, medium, or high risk of bias.

Data Synthesis Strategy

Findings were synthesized by target population characteristics, study type, and outcome. Outcome measures were produced for each study by calculating ORs and 95% confidence intervals, using recommended gestational weight gain within each BMI category as the reference. When 2 or more studies assessed the same outcome, results were pooled using both fixed- and random-effects meta-analysis. There were no significant differences between fixed- and random-effects analyses. Random effects are presented given heterogeneity among studies. Extracted pooled ORs for individual outcomes were combined to construct summary pooled ORs. Crude data were used where possible, given variable control for confounding factors. However, some articles presented adjusted ORs only.[17-24] Absolute risk differences (ARDs) per live birth were calculated from event rates (available for a subset of studies) using random-effects meta-analysis.

Heterogeneity was assessed using the I^2 statistic, where $I^2 > 50\%$ indicated substantial heterogeneity.[25] Metaregression was performed to investigate sources of heterogeneity (percentage of smokers during pregnancy, mean age, and percentage of nulliparous women). Race/ethnicity data were not available for the metaregression. Where 5 or more studies were

available, publication bias was assessed using Egger test plots.[26,27] Statistical significance was defined as 2-sided $P < .05$. Statistical analysis used Stata software version 14 (StataCorp LP).

A subgroup analysis was performed in specific population groups identified a priori (studies using Chinese or Korean BMI categories, not presented herein). Obesity subclasses were included after reviewing studies that stratified by obesity class. Tests for trend based on the Cochran-Armitage test in Stata were used to assess trends in this subgroup analysis.

Results

Study Selection

Of 5874 studies identified by the initial search, 302 were selected for full-text review; 261 of these were excluded, leaving 41 (Figure 1). These studies grouped women by prepregnancy BMI category, stratified by total gestational weight gain. One study[28] did not meet inclusion criteria as published; however, prior collaboration had made data available in the required format. Of 41 identified studies, 18 were excluded because data could not be obtained in the required format. Of these 18 studies, authors of 15 were contacted and unable to reanalyze and authors of 3 were not contacted from the updated search because of insufficient time prior to publication (eAppendix 2 in the Supplement). Overall, 23 cohort studies[17-24,28-42] were included, involving 1 309 136 women. Of these 23 studies, 7 were included without contacting the authors because data were in the required format. Of 16 authors contacted, 13 reanalyzed data and were included; 3 provided additional information, thereby avoiding reanalysis.

Study Characteristics

Table 2 and **Table 3** list characteristics of the studies (descriptive characteristics are shown in eTable 1 in the Supplement). Eighteen studies were retrospective, and 5 were prospective.[20,29,32,33,42] Ten were from the United States,[18-20,23,28,31,35,38,40,41] 8 were from Asia (4 from China,[21,29,32,36] 2 from Korea,[34,39] and 1 each from Taiwan[24] and Japan[22]), and 5 were from Europe (1 each from Norway,[33] Belgium,[30] Italy,[37] Denmark,[42] and Sweden[17]). Sample sizes ranged from 1034 to 570 672 women.

Underweight women composed 7% (n = 94 399); normal-weight women, 55% (n = 720 456); overweight women, 18% (n = 235 295); and obese women, 20% (n = 258 986). Gestational weight gain was below, within, or above guidelines in 23% (n = 300 723), 30% (n = 387 409), and 47% (n = 621 004), respectively.

Figure 2 shows pooled ORs for primary and secondary outcomes. eFigure 1 in the Supplement shows pooled ORs for individual outcomes. eTable 2 in the Supplement reports event rates. eTable 3 and eFigure 2 in the Supplement report ARDs and *P* values. The ARDs are expressed as percentage difference per live birth.

Primary Outcomes

Small for Gestational Age

Eleven studies assessed SGA, defined as birth weight less than the 10th percentile for gestational age in 5 studies.[22,31,36,39,40] Four studies defined SGA by additionally accounting for sex,[24,28,33,38] 1 for sex and race/ethnicity,[41] and another for sex, race, and parity.[23]

Across BMI categories, gestational weight gain below guidelines was associated with higher risk for SGA than gestational weight gain within guidelines (OR, 1.53 [95% CI, 1.44 to 1.64]; I^2 = 82.8%; ARD, 5% [95% CI, 4% to 6%]). This association was greatest in lower prepregnancy BMI (underweight: OR, 1.89 [95% CI, 1.67 to 2.14]; ARD, 8% [95% CI, 6% to 11%]; normal weight: OR, 1.63 [95% CI, 1.54 to 1.71]; ARD, 5% [95% CI, 4% to 6%]; overweight: OR, 1.34 [95% CI, 1.24 to 1.44]; ARD, 3% [95% CI, 3% to 4%]; and obese: OR, 1.24 [95% CI, 1.06 to 1.45]; ARD, 2% [95% CI, 2% to 3%]).

Compared with gestational weight gain within guidelines, gain above guidelines was associated with lower risk for SGA (OR, 0.66 [95% CI, 0.63 to 0.69]; I^2 = 56%; ARD, −3% [95% CI, −4% to −2%]). The association was similar across BMI categories (underweight: OR, 0.62 [95% CI, 0.53 to 0.72]; ARD, −6% [95% CI, −8% to −3%]; normal weight: OR, 0.65 [95% CI, 0.62 to 0.68]; ARD, −2% [95% CI, −3% to−1%]; overweight: OR, 0.65 [95% CI, 0.59 to 0.71]; ARD, −3% [95% CI, −4% to −2%]; and obese: OR, 0.72 [95% CI, 0.65 to 0.80]; ARD, −2% [95% CI, −3% to −1%]).

Preterm Birth

Four studies assessed preterm birth (<37 weeks' gestation). Of these, 3 did not specify whether the preterm birth was spontaneous or induced[28,31,36] and 1 specified spontaneous and induced combined.[22]

Compared with gestational weight gain within guidelines, weight gain below guidelines was associated with higher risk for preterm birth (OR, 1.70 [95% CI, 1.32 to 2.20]; I^2 = 97.3%; ARD, 5% [95% CI, 3% to 8%]). This association was greatest with lower BMI (underweight: OR, 2.41 [95% CI, 1.01 to 5.73]; ARD, 8% [95% CI, 1% to 15%]; normal weight: OR, 1.96 [95% CI, 1.17 to 3.29]; ARD, 6% [95% CI, 0% to 11%]; overweight: OR, 1.55 [95% CI, 1.10 to 2.19]; ARD, 4% [95% CI, −1% to 9%]; and obese: OR, 1.20 [95% CI, 1.03 to 1.40]; ARD, 3% [95% CI, 1% to 5%]).

Gestational weight gain above guidelines was associated with lower risk for preterm birth (OR, 0.77 [95% CI, 0.69 to 0.86]; I^2 = 78.7%; ARD, −2% [95% CI, −2% to −1%]). This association was significant for normal-weight and overweight women (underweight: OR, 0.80 [95% CI, 0.50 to 1.28]; ARD, −1% [95% CI, −3% to 0%]; normal weight: OR, 0.76 [95% CI, 0.59 to 0.97]; ARD, −1% [95% CI, −2% to 0%]; overweight: OR, 0.70 [95% CI, 0.53 to 0.93]; ARD, −3% [95% CI, −5% to −1%]; and obese: OR, 0.76 [95% CI, 0.62 to 0.93]; ARD, −2% [95% CI, −5% to 2%]).

Large for Gestational Age

Thirteen studies assessed LGA, defined as birth weight greater than the 90th percentile for gestational age in 6 studies.[22,31,34,36,39,40] Four defined LGA by additionally ac-

Table 2. Characteristic of 19 Studies That Stratified by Prepregnancy BMI Categories[a]

Source	Study Period, Design	Total No. of Women	Setting	Outcomes	Prepregnancy BMI Category	Women, No.	No. of Events/No. of Live Births (%) by Gestational Weight Gain Category[b]		
							Below Guidelines	Within Guidelines	Above Guidelines
Durst et al,[23] 2016 (United States)	2000-2014, Retrospective	5651	University of Alabama at Birmingham	SGA, LGA, cesarean delivery, macrosomia	Overweight	5651	NR	NR	NR
Enomoto et al,[22] 2016 (Japan)	2013, Retrospective	97 157	Japan Society of Obstetrics and Gynecology Registry system with 280 participating hospitals	SGA	Underweight	17 724	2032/13 529 (15.0)	286/3783 (7.6)	23/412 (5.6)
					Normal weight	69 126	4575/44 189 (10.4)	1254/20 835 (6.0)	163/4102 (4.0)
					Overweight	7502	275/2990 (9.2)	179/2810 (6.4)	89/1702 (5.2)
					Obese	2805	112/1297 (8.6)	48/853 (5.6)	38/655 (5.8)
				LGA	Underweight	17 724	518/13 529 (3.8)	388/3783 (10.3)	61/412 (14.8)
					Normal weight	69 126	3322/44 189 (7.5)	2754/20 835 (13.2)	868/4102 (21.1)
					Overweight	7502	363/2990 (12.1)	489/2810 (17.4)	450/1702 (26.4)
					Obese	2805	213/1297 (16.4)	206/853 (24.2)	215/655 (32.8)
				Preterm birth	Underweight	17 724	1979/13 529 (14.6)	167/3783 (4.4)	8/412 (1.9)
					Normal weight	69 126	5891/44 189 (13.3)	994/20 835 (4.8)	178/4102 (4.3)
					Overweight	7502	508/2990 (17.0)	240/2810 (8.5)	125/1702 (7.3)
					Obese	2805	199/1297 (15.3)	95/853 (11.1)	44/655 (6.7)
				Cesarean delivery	Underweight	17 724	3174/13 539 (23.4)	739/3783 (19.5)	82/412 (19.9)
					Normal weight	69 126	12 446/44 189 (28.2)	5062/20 835 (24.3)	1119/4102 (27.3)
					Overweight	7502	1151/2990 (38.5)	991/2810 (35.3)	617/1702 (36.3)
					Obese	2805	542/1297 (41.8)	367/853 (43.0)	296/655 (45.2)
				Macrosomia	Underweight	17 724	16/13 529 (0.1)	20/3783 (0.5)	11/412 (2.7)
					Normal weight	69 126	149/44 189 (0.3)	214/20 835 (1.0)	111/4102 (2.7)
					Overweight	7502	34/2990 (1.1)	35/2810 (1.3)	63/1702 (3.7)
					Obese	2805	21/1297 (1.6)	37/853 (4.3)	37/655 (5.7)
Hung and Hsieh,[24] 2016 (Taiwan)	2009-2015, Retrospective	10 973	Taipei Chang Gung Memorial Hospital	SGA	Underweight	1556	117/691 (16.9)	63/718 (8.8)	10/147 (6.8)
					Normal weight	8247	199/2304 (8.7)	233/3827 (6.1)	90/2116 (4.3)
					Overweight + obese	1170	121/161 (75.2)	23/403 (5.7)	24/606 (4.0)
				LGA	Underweight	1556	8/691 (1.2)	34/718 (4.7)	18/147 (12.2)
					Normal weight	8247	103/2304 (4.5)	306/3827 (8.0)	274/2116 (12.9)
					Overweight + obese	1170	18/161 (11.2)	61/403 (15.1)	107/606 (17.7)
				Cesarean delivery	Underweight	1556	143/691 (20.7)	151/718 (21.0)	54/147 (36.7)
					Normal weight	8247	412/2304 (17.9)	882/3827 (23.1)	644/2116 (30.4)
					Overweight + obese	1170	34/161 (21.1)	89/403 (22.1)	197/606 (32.5)
				Macrosomia	Underweight	1556	3/691 (0.4)	4/718 (0.6)	5/147 (3.4)
					Normal weight	8247	17/2304 (0.7)	63/3827 (1.7)	74/2116 (3.5)
					Overweight + obese	1170	6/161 (3.7)	9/403 (2.2)	30/606 (5.0)

(continued)

Table 2. Characteristic of 19 Studies That Stratified by Prepregnancy BMI Categories[a] (continued)

Source	Study Period, Design	Total No. of Women	Setting	Outcomes	Prepregnancy BMI Category	Women, No.	No. of Events/No. of Live Births (%) by Gestational Weight Gain Category[b]		
							Below Guidelines	Within Guidelines	Above Guidelines
Xiong et al,[29] 2016 (China)[c]	2012-2013, Prospective	57 891	Hospitals and community centers	Cesarean delivery	Underweight	10 121			
					Normal weight	44 522	NR	NR	NR
					Overweight	2877			
					Obese	371			
Shin and Song,[31] 2015 (United States)	2004-2011, Retrospective	219 868	Pregnancy Risk Assessment Monitoring System	SGA, preterm birth, LGA	Underweight	11 865			
					Normal weight	113 523	NR	NR	NR
					Overweight	51 517			
					Obese	42 963			
Wen and Lu,[21] 2015 (China)[c]	2009-2013, Retrospective	13 776	Jishuitan Hospital	Preterm birth	Underweight	0			
					Normal weight	13 776	NR	NR	NR
					Overweight	0			
					Obese	0			
Yang et al,[32] 2015 (China)[c]	2011-2013, Prospective	85 765	Wuhan Women and Children Health Care Center	Macrosomia	Underweight	14 477	13/158 (8.2)	93/4723 (2.0)	449/7139 (6.3)
					Normal weight	65 536	361/11627 (3.1)	623/14 103 (4.4)	3387/33 647 (10.1)
					Overweight + obese	5752	35/573 (6.1)	79/982 (8.0)	551/3299 (16.7)
Badon et al,[20] 2014 (United States)	2000-2006, Prospective	5297	North American Field Centers, HAPO Study	LGA	Underweight	179			
					Normal weight	3013	NR	NR	NR
					Overweight	1322			
					Obese	783			
Chihara et al,[19] 2014 (United States)	2003-2005, Retrospective	19 130	Hawaii's Special Supplemental Nutrition Program for Women, Infants, and Children	Macrosomia	Underweight	1153			
					Normal weight	9291	NR	NR	NR
					Overweight	4391			
					Obese	4295			

(continued)

Table 2. Characteristic of 19 Studies That Stratified by Prepregnancy BMI Categories[a] (continued)

Source	Study Period, Design	Total No. of Women	Setting	Outcomes	Prepregnancy BMI Category	Women, No.	No. of Events/No. of Live Births (%) by Gestational Weight Gain Category[b]		
							Below Guidelines	Within Guidelines	Above Guidelines
Haugen et al,[33] 2014 (Norway)[d]	1999-2008, Prospective	56 082	Norwegian Mother and Child Cohort Study	SGA	Underweight	1610	143/457 (31.3)	144/751 (19.2)	37/402 (9.2)
					Normal weight	37 315	1327/7798 (17.0)	1662/14 904 (11.2)	1042/14 613 (7.1)
					Overweight	12 181	156/1037 (15.0)	281/2485 (11.3)	557/8659 (6.4)
					Obese	4976	97/878 (11.1)	99/1054 (9.4)	204/3044 (6.7)
				LGA	Underweight	1610	4/457 (0.9)	21/751 (2.8)	30/402 (7.5)
					Normal weight	37 315	250/7798 (3.2)	914/14 904 (6.1)	1796/14 613 (12.3)
					Overweight	12 181	62/1037 (6.0)	212/2485 (8.5)	1370/8659 (15.8)
					Obese	4976	90/878 (10.3)	154/1054 (14.6)	676/3044 (22.2)
				Cesarean delivery	Underweight	1610	44/457 (9.6)	71/751 (9.5)	47/402 (11.7)
					Normal weight	37 315	726/7798 (9.3)	1526/14 904 (10.2)	1836/14 613 (12.6)
					Overweight	12 181	137/1037 (13.2)	327/2485 (13.2)	1439/8659 (16.6)
					Obese	4976	173/878 (19.7)	227/1054 (21.5)	703/3044 (23.1)
				Macrosomia	Underweight	1610	15/457 (3.3)	68/751 (9.1)	62/402 (15.4)
					Normal weight	37 315	782/7798 (10.0)	2573/14 904 (17.3)	4014/14 613 (27.5)
					Overweight	12 181	160/1037 (15.4)	530/2485 (21.3)	2472/8659 (28.5)
					Obese	4976	206/878 (23.5)	300/1054 (28.5)	1822/3044 (59.9)
Lee et al,[34] 2014 (Korea)[e]	2010-2012, Retrospective	16 297	Single medical center	LGA	Underweight	2655			
					Normal weight	12 250		NR	NR
					Overweight	1191	NR		
					Obese	201			

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Table 2. Characteristic of 19 Studies That Stratified by Prepregnancy BMI Categories[a] (continued)

Source	Study Period, Design	Total No. of Women	Setting	Outcomes	Prepregnancy BMI Category	Women, No.	No. of Events/No. of Live Births (%) by Gestational Weight Gain Category[b]		
							Below Guidelines	Within Guidelines	Above Guidelines
Black et al,[28] 2013 (United States)	2005-2010, Retrospective	9835	Kaiser Permanente Southern California	SGA	Underweight	179	11/55 (20.0)	9/75 (12.0)	3/51 (5.9)
					Normal weight	3805	158/1031 (15.3)	125/1388 (9.0)	114/1386 (8.2)
					Overweight	3116	58/424 (13.7)	70/815 (8.6)	119/1877 (6.3)
					Obese	2735	57/608 (9.4)	54/648 (8.3)	80/1479 (5.4)
				LGA	Underweight	179	0/55	4/73 (5.5)	2/51 (3.9)
					Normal weight	3805	2/1031 (0.2)	46/1388 (3.3)	113/1386 (8.2)
					Overweight	3116	15/424 (3.5)	39/815 (4.8)	205/1877 (10.9)
					Obese	2735	32/608 (5.3)	52/648 (8.0)	235/1479 (15.9)
				Preterm birth	Underweight	179	10/55 (18.2)	2/73 (2.7)	1/51 (2.0)
					Normal weight	3805	127/1031 (12.3)	77/1388 (5.5)	45/1386 (3.2)
					Overweight	3116	54/424 (12.7)	76/815 (9.3)	87/1877 (4.6)
					Obese	2735	53/608 (8.7)	49/648 (7.6)	80/1479 (5.4)
				Cesarean delivery	Underweight	179	6/55 (10.9)	14/73 (19.2)	13/51 (25.5)
					Normal weight	3805	219/1031 (21.2)	293/1388 (21.1)	339/1386 (24.5)
					Overweight	3116	105/424 (24.8)	200/815 (24.5)	589/1877 (31.4)
					Obese	2735	184/608 (30.3)	216/648 (33.3)	575/1479 (38.9)
				Macrosomia	Underweight	179	0/55	5/73 (6.8)	3/51 (5.9)
					Normal weight	3805	28/1031 (2.7)	63/1388 (4.5)	148/1386 (10.7)
					Overweight	3116	17/424 (4.0)	46/815 (5.6)	225/1877 (12.0)
					Obese	2735	38/608 (6.3)	65/648 (10.0)	265/1479 (17.9)

(continued)

Table 2. Characteristic of 19 Studies That Stratified by Prepregnancy BMI Categories[a] (continued)

Source	Study Period, Design	Total No. of Women	Setting	Outcomes	Prepregnancy BMI Category	Women, No.	No. of Events/No. of Live Births (%) by Gestational Weight Gain Category[b]		
							Below Guidelines	Within Guidelines	Above Guidelines
Li et al,[36] 2013 (China)[f]	2009-2011, Retrospective	33 973	Tianjin Women's and Children's Health Center	SGA	Underweight	3732	151/733 (20.6)	323/1820 (17.7)	114/1179 (9.7)
					Normal weight	24 262	383/2777 (13.8)	817/9347 (8.7)	935/12 138 (7.7)
					Overweight	4998	6/86 (7.0)	54/665 (8.1)	277/4247 (6.5)
					Obese	981	1/16 (6.3)	6/54 (11.1)	44/911 (4.8)
				LGA	Underweight	3732	15/733 (2.0)	49/1820 (2.7)	77/1179 (6.5)
					Normal weight	24 262	15/2777 (0.5)	625/9347 (6.7)	1549/12 138 (12.8)
					Overweight	4998	32/86 (37.2)	86/665 (12.9)	741/4247 (17.4)
					Obese	981	4/16 (25.0)	10/54 (18.5)	228/911 (25.0)
				Preterm birth	Underweight	3732	31/733 (4.2)	45/1820 (2.5)	22/1179 (1.9)
					Normal weight	24 262	142/2777 (5.1)	322/9347 (3.4)	248/12 138 (2.0)
					Overweight	4998	5/86 (5.8)	37/665 (5.6)	134/4247 (3.2)
					Obese	981	1/16 (6.3)	2/54 (3.7)	61/911 (6.7)
				Cesarean delivery	Underweight	3732	375/733 (51.2)	945/1820 (51.9)	723/1179 (61.3)
					Normal weight	24 262	1677/2777 (60.4)	5645/9347 (60.4)	8208/12 138 (67.6)
					Overweight	4998	62/86 (72.1)	480/665 (72.2)	3348/4247 (78.8)
					Obese	981	11/16 (68.8)	50/54 (92.6)	774/911 (85.0)
				Macrosomia	Underweight	3732	141/733 (19.2)	53/1820 (2.9)	751/1179 (63.7)
					Normal weight	24 262	145/2777 (5.2)	581/9347 (6.2)	1464/12 138 (12.1)
					Overweight	4998	6/86 (7.0)	71/665 (10.7)	687/4247 (16.2)
					Obese	981	4/16 (25.0)	9/54 (16.7)	203/911 (22.3)
Di Benedetto et al,[37] 2012 (Italy)	2004-2009, Retrospective	2225	University hospital	Macrosomia, cesarean delivery	Underweight	89			
					Normal weight	1468	NR	NR	NR
					Overweight	493			
					Obese	175			
Simas et al,[38] 2012 (United States)	2006-2010, Retrospective	11 203	University hospital	SGA, LGA	Underweight	427			
					Normal weight	5707	NR	NR	NR
					Overweight	2756			
					Obese	2313			
Park et al,[39] 2011 (Korea)[e]	2005-2007, Retrospective	2311	University hospital	SGA, LGA, macrosomia, cesarean delivery	Underweight	385			
					Normal weight	1666	NR	NR	NR
					Overweight	221			
					Obese	39			

(continued)

Table 2. Characteristic of 19 Studies That Stratified by Prepregnancy BMI Categories[a] (continued)

Source	Study Period, Design	Total No. of Women	Setting	Outcomes	Prepregnancy BMI Category	Women, No.	No. of Events/No. of Live Births (%) by Gestational Weight Gain Category[b]			
							Below Guidelines	Within Guidelines	Above Guidelines	
Park et al,[40] 2011 (United States)	2004-2007, Retrospective	560 672	Florida birth certificate data	SGA	Underweight	28 119	1987/7555 (26.3)	1815/11 676 (15.5)	865/8888 (9.7)	
					Normal weight	305 295	11 213/71 025 (15.8)	10 324/103 613 (10.0)	8460/130 657 (6.5)	
					Overweight	135 668	2167/16 723 (13.0)	3033/30 731 (9.9)	5516/88 214 (6.3)	
					Obese	101 590	2157/19 740 (10.9)	1501/17 350 (8.7)	4147/64 500 (6.4)	
				LGA	Underweight	28 119	84/7555 (1.1)	366/11 676 (3.1)	669/8888 (7.5)	
					Normal weight	305 295	2479/71 025 (3.5)	6183/103 613 (6.0)	15 146/130 657 (11.6)	
					Overweight	135 668	851/16 723 (5.1)	2329/30 731 (7.6)	12 417/88 214 (14.1)	
					Obese	101 590	16 571/19 740 (83.9)	1906/17 350 (11.0)	10 794/64 500 (16.7)	
Vesco et al,[41] 2011 (United States)	2000-2005, Retrospective	2080	Kaiser Permanente group practice	SGA, LGA, macrosomia	Underweight	0				
					Normal weight	0	NR	NR	NR	
					Overweight	0				
					Obese	2080				
Rode et al,[42] 2007 (Denmark)	1996-1998, Prospective	2248	University hospital	Macrosomia	Underweight	128				
					Normal weight	1654	NR	NR	NR	
					Overweight	349				
					Obese	117				

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); HAPO, Hyperglycemia and Adverse Pregnancy Outcome; LGA, large for gestational age; NR, not reported; SGA, small for gestational age.

[a] Unless indicated otherwise, prepregnancy categories of BMI categories were according to World Health Organization (WHO) categories as follows: BMI for underweight, less than 18.5; normal weight, 18.5 to 24.9; overweight, 25 to 29.9; and obese, 30 or higher.

[b] Refer to eFigure 1 in the Supplement for odds ratios.

[c] Data according to Chinese BMI categories only (BMI for underweight, <18.5; normal weight, 18.5-23.9; overweight, 24-28; and obese, ≥28).

[d] Sample size changed when additional data were provided.

[e] Data according to both Korean BMI categories (BMI for underweight, <18.5; normal weight, 18.5-22.9; overweight, 23-25; and obese ≥25) and WHO BMI categories (WHO reported herein).

[f] Data according to both Chinese and WHO BMI categories (WHO reported herein).

Table 3. Characteristic of 4 Studies That Stratified by Prepregnancy Obesity Class

Source	Study Period, Design	Total No. of Women	Setting	Outcomes	Prepregnancy Obesity Class[a]	Women, No.	No. of Events/No. of Live Births (%) by Gestational Weight Gain Category			
							Loss	Gain Below Guidelines	Gain Within Guidelines	Gain Above Guidelines
Bogaerts et al,[30] 2015 (Belgium)	2009-2011, Retrospective	18 053	Flemish Centre for the Study of Perinatal Epidemiology	SGA	1	12 994	52/420 (12.4)	164/1554 (10.6)	316/3585 (8.8)	421/7435 (5.7)
					2	3787	32/263 (12.2)	54/648 (8.3)	80/1156 (6.9)	95/1720 (5.5)
					3	1272	16/171 (9.4)	16/291 (5.5)	22/379 (5.8)	20/431 (4.6)
				LGA	1	12 994	29/420 (6.9)	152/1554 (9.8)	474/3585 (13.2)	1468/7438 (19.7)
					2	3787	28/263 (10.6)	78/648 (12.0)	189/1156 (16.3)	409/1720 (23.8)
					3	1272	19/171 (11.1)	59/291 (20.3)	97/379 (25.6)	122/431 (28.3)
				Cesarean delivery	1	12 994	101/420 (24.0)	353/1554 (22.7)	844/3585 (23.5)	2020/7435 (27.2)
					2	3787	65/263 (24.7)	153/648 (23.6)	344/1156 (29.8)	561/1720 (32.6)
					3	1272	61/171 (35.7)	98/291 (33.7)	132/379 (34.8)	168/431 (39.0)
				Macrosomia	1	12 994	29/420 (6.9)	155/1554 (10.0)	435/3585 (12.1)	1384/7435 (18.6)
					2	3787	23/263 (8.7)	76/648 (11.7)	165/1156 (14.3)	366/1720 (21.3)
					3	1272	11/171 (6.4)	49/291 (16.8)	89/379 (23.5)	100/431 (23.2)
Swank et al,[35] 2014 (United States)	2007, Retrospective	1034	California birth certificate data	Cesarean delivery	3	1034	96/170 (56.5)	134/226 (59.3)	139/243 (57.2)	253/395 (64.1)
				Macrosomia	3	1034	14/170 (8.2)	35/226 (15.5)	52/243 (21.4)	104/395 (26.3)
Kominiarek et al,[18] 2013 (United States)[b]	2002-2008, Retrospective	21 020	12 Institutions (19)	SGA	1	12 005	66/406 (16.3)	135/1352 (10.0)	187/1931 (9.7)	549/8316 (6.6)
					2	5320	57/354 (16.1)	100/918 (10.9)	85/1018 (8.3)	193/3030 (6.4)
					3	3695	57/486 (11.7)	72/748 (10.4)	51/664 (7.7)	119/1797 (6.6)
				LGA	1	12 005	13/406 (3.2)	76/1352 (5.6)	119/1931 (6.2)	1029/8316 (12.4)
					2	5320	17/354 (4.8)	67/918 (7.3)	101/1018 (9.9)	435/3030 (14.4)
					3	3695	31/486 (6.4)	77/748 (10.3)	85/664 (12.8)	315/1797 (17.5)
				Cesarean delivery	1	12 005	64/406 (15.8)	292/1352 (21.6)	425/1931 (22.0)	1816/8316 (21.8)
					2	5320	86/354 (24.3)	237/918 (25.8)	277/1018 (27.2)	754/3030 (24.9)
					3	3695	144/486 (29.6)	222/748 (29.7)	233/664 (35.1)	562/1797 (31.3)
				Macrosomia	1	12 005	2/406 (0.5)	7/1352 (0.5)	15/1931 (0.8)	191/8316 (2.3)
					2	5320	1/354 (0.3)	8/918 (0.9)	13/1018 (1.3)	87/3030 (2.9)
					3	3695	7/486 (1.4)	11/748 (1.5)	19/664 (2.9)	66/1797 (3.7)
Blomberg,[17] 2011 (Sweden)	1993-2008, Retrospective	46 595	Swedish Medical Birth Register	SGA	1	32 991	51/1341 (3.8)	88/3105 (2.8)	162/8807 (1.8)	232/19 738 (1.2)
					2	10 068	13/798 (1.6)	40/1466 (2.7)	58/2927 (2.0)	70/4877 (1.4)
					3	3536	19/517 (3.7)	16/616 (2.6)	17/1002 (1.7)	27/1401 (1.9)
				LGA	1	32 991	87/1341 (6.5)	228/3105 (7.3)	757/8807 (8.6)	2674/19 738 (13.5)
					2	10 068	57/798 (7.1)	142/1466 (9.7)	361/2927 (12.3)	853/4877 (17.5)
					3	3536	57/517 (11.0)	88/616 (14.3)	155/1002 (15.5)	278/1401 (19.8)
				Cesarean delivery	1	32 991	206/1341 (15.4)	554/3105 (17.8)	1675/8807 (19.0)	4431/19 738 (22.4)
					2	10 068	135/798 (16.9)	306/1466 (20.9)	713/2927 (24.4)	1312/4877 (26.9)
					3	3536	125/517 (24.2)	148/616 (24.0)	289/1002 (28.8)	439/1401 (31.3)

Abbreviations: LGA, large for gestational age; SGA, small for gestational age.

[a] Class 1 indicates a body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) of 30 to 34.9; class 2, BMI of 35 to 39.9; and class 3, BMI of 40 or higher.

[b] Sample size changed when additional data were provided, and the odds ratios were not recalculated.

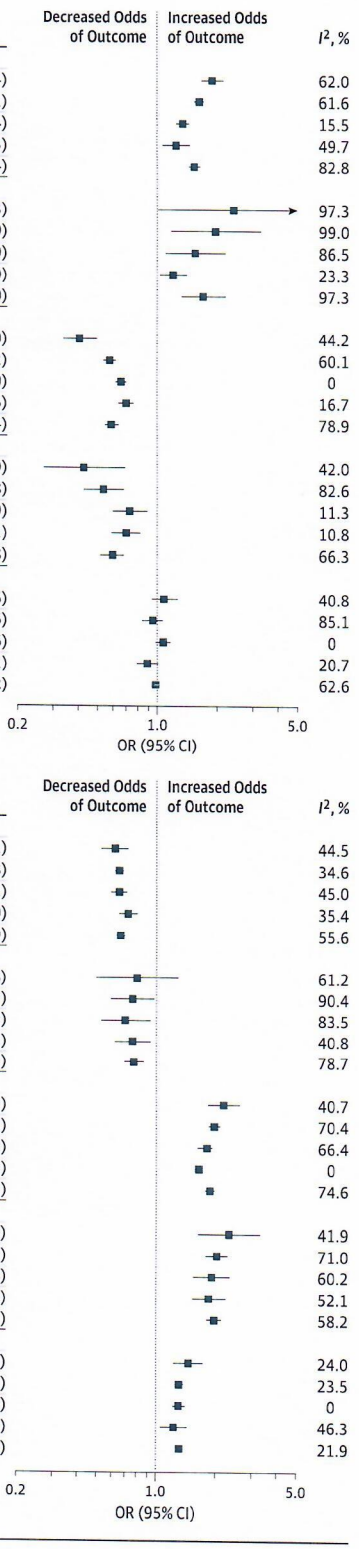
Figure 2. Summary of Pooled Odds Ratios (ORs) for the Association Between Gestational Weight Gain Below and Above Guidelines With Adverse Outcomes

A Below recommended gestational weight gain

Outcomes by BMI category	Studies, No.	Women, No.	OR (95% CI)	I^2, %
SGA	11	1019805		
<18.5	9	28551	1.89 (1.67-2.14)	62.0
18.5-24.9	9	162331	1.63 (1.54-1.71)	61.6
25-29.9	9	27634	1.34 (1.24-1.44)	15.5
≥30	9	31526	1.24 (1.06-1.45)	49.7
Overall			1.53 (1.44-1.64)	82.8
Preterm birth	4	360833		
<18.5	4	19941	2.41 (1.01-5.73)	97.3
18.5-24.9	4	79537	1.96 (1.17-3.29)	99.0
25-29.9	4	6681	1.55 (1.10-2.19)	86.5
≥30	4	8598	1.20 (1.03-1.40)	23.3
Overall			1.70 (1.32-2.20)	97.3
LGA	13	1041399		
<18.5	9	29596	0.41 (0.34-0.50)	44.2
18.5-24.9	11	166212	0.58 (0.54-0.62)	60.1
25-29.9	11	27899	0.66 (0.62-0.70)	0
≥30	12	31675	0.70 (0.64-0.76)	16.7
Overall			0.59 (0.55-0.64)	78.9
Macrosomia	11	241665		
<18.5	7	15617	0.43 (0.27-0.69)	42.0
18.5-24.9	9	59503	0.54 (0.43-0.68)	82.6
25-29.9	9	4935	0.73 (0.60-0.89)	11.3
≥30	9	4740	0.70 (0.59-0.82)	10.8
Overall			0.60 (0.52-0.68)	66.3
Cesarean delivery	8	218207		
<18.5	7	15645	1.08 (0.94-1.26)	40.8
18.5-24.9	7	59100	0.95 (0.84-1.06)	85.1
25-29.9	7	2186	1.07 (0.98-1.16)	0
≥30	7	4336	0.89 (0.79-1.01)	20.7
Overall			0.98 (0.96-1.02)	62.6

B Above recommended gestational weight gain

Outcomes by BMI category	Studies, No.	Women, No.	OR (95% CI)	I^2, %
SGA	11	1019805		
<18.5	9	13711	0.62 (0.53-0.72)	44.5
18.5-24.9	9	88780	0.65 (0.62-0.68)	34.6
25-29.9	9	110665	0.65 (0.59-0.71)	45.0
≥30	10	103820	0.72 (0.65-0.80)	35.4
Overall			0.66 (0.63-0.69)	55.6
Preterm birth	4	360833		
<18.5	4	4063	0.80 (0.50-1.28)	61.2
18.5-24.9	4	60324	0.76 (0.59-0.97)	90.4
25-29.9	4	11162	0.70 (0.53-0.93)	83.5
≥30	4	30809	0.76 (0.62-0.93)	40.8
Overall			0.77 (0.69-0.86)	78.7
LGA	13	1041399		
<18.5	10	13978	2.17 (1.81-2.60)	40.7
18.5-24.9	11	215994	1.95 (1.83-2.08)	70.4
25-29.9	11	142236	1.79 (1.61-1.98)	66.4
≥30	11	104459	1.63 (1.56-1.70)	0
Overall			1.85 (1.76-1.95)	74.6
Macrosomia	11	241665		
<18.5	7	2214	2.31 (1.62-3.29)	41.9
18.5-24.9	9	35928	2.01 (1.77-2.27)	71.0
25-29.9	9	17627	1.90 (1.54-2.33)	60.2
≥30	9	1035	1.83 (1.52-2.22)	52.1
Overall			1.95 (1.79-2.11)	58.2
Cesarean delivery	8	218207		
<18.5	7	2227	1.45 (1.22-1.71)	24.0
18.5-24.9	7	35416	1.30 (1.24-1.36)	23.5
25-29.9	7	17419	1.29 (1.21-1.39)	0
≥30	7	9012	1.22 (1.05-1.42)	46.3
Overall			1.30 (1.25-1.35)	21.9



Pooled ORs are shown for the association between gestational weight gain below (A) and above (B) guidelines with adverse outcomes. Reference group is women with recommended weight gain in each category of body mass index (BMI; calculated as weight in kilograms divided by height in meters squared). For each outcome, the sample size represents the total number of women in the studies that assessed the outcome. For each BMI category, the sample size represents the total number of women with gestational weight gain below or above the guidelines. LGA indicates large for gestational age; SGA, small for gestational age.

counting for infant sex,[24,28,33,38] 1 for sex and race/ethnicity,[41] 1 for sex, race, and parity,[23] and 1 for sex, parity, and study center.[20]

Gestational weight gain below guidelines was associated with lower risk of LGA than gestational weight gain within guidelines (OR, 0.59 [95% CI, 0.55 to 0.64]; I^2 = 78.9%; ARD, −2% [95% CI, −10% to −6%]). This was significant for underweight and normal-weight women (underweight: OR, 0.41 [95% CI, 0.34 to 0.50]; ARD, −3% [95% CI, −5% to −1%]; normal weight: OR, 0.58 [95% CI, 0.54-0.62]; ARD, −3% [95% CI, −4% to −2%]; overweight: OR, 0.66 [95% CI, 0.62 to 0.70]; ARD, −11% [95% CI, −33% to 10%]; and obese: OR, 0.70 [95% CI, 0.64 to 0.76]; ARD, 13% [95% CI, −34% to 60%]).

Gestational weight gain above guidelines was associated with higher risk of LGA (OR, 1.85 [95% CI, 1.76 to 1.95]; I^2 = 74.6%; ARD, 4% [95% CI, 2% to 5%]). The association increased as BMI decreased (underweight: OR, 2.17 [95% CI, 1.81 to 2.60]; ARD, 4% [95% CI, 4% to 5%]; normal weight: OR, 1.95 [95% CI, 1.83 to 2.08]; ARD, 6% [95% CI, 5% to 7%]; overweight: OR, 1.79 [95% CI, 1.61 to 1.98]; ARD, −2% [95% CI, −14% to 9%]; and obese: OR, 1.63 [95% CI, 1.56 to 1.70]; ARD, 7% [95% CI, 5% to 8%]).

Secondary Outcomes

Macrosomia

Of 11 studies assessing macrosomia, 10 defined macrosomia as birth weight greater than 4000 g,[19,22-24,28,33,36,37,39,42] and 1 defined it as birth weight greater than 4500 g.[41]

Gestational weight gain below guidelines was associated with lower risk of macrosomia (OR, 0.60 [95% CI, 0.52 to 0.68]; I^2 = 66.3%; ARD, −2% [95% CI, −3% to −1%]). The association was strongest in underweight women (underweight: OR, 0.43 [95% CI, 0.27 to 0.69]; ARD, −1% [95% CI, −3% to 0%]; normal weight: OR, 0.54 [95% CI, 0.43 to 0.68]; ARD, −2% [95% CI, −5% to 1%]; overweight: OR, 0.73 [95% CI, 0.60 to 0.89]; ARD, −2% [95% CI, −6% to 2%]; and obese: OR, 0.70 [95% CI, 0.59 to 0.82]; ARD, −3% [−4% to −2%]).

Gestational weight gain above guidelines was associated with higher risk of macrosomia (OR, 1.95 [95% CI, 1.79 to 2.11]; I^2 = 58.2%; ARD, 6% [95% CI, 4% to 9%]). This association was strongest in underweight women according to the ORs, and all associations were significant according to the ARDs (underweight: OR, 2.31 [95% CI, 1.62 to 3.29]; ARD, 3% [95% CI, 2% to 4%]; normal weight: OR, 2.01 [95% CI, 1.77 to 2.27]; ARD, 10% [95% CI, 5% to 15%]; overweight: OR, 1.90 [95% CI, 1.54 to 2.33]; ARD, 5% [95% CI, 1% to 10%]; and obese: OR, 1.83 [95% CI, 1.52 to 2.22]; ARD, 6% [95% CI, 1% to 12%]).

Cesarean Delivery

Eight studies assessed cesarean delivery. Seven included emergency and elective deliveries,[22,28,29,33,36,37,39] and 1 did not specify.[24] One study[28] included repeated cesarean delivery (total cesarean deliveries), 1 included primary cesarean delivery only,[24] and 6 did not distinguish these.

Gestational weight gain below guidelines was not significantly associated with cesarean delivery (OR, 0.98 [95% CI, 0.96 to 1.02]; I^2 = 62.6%; ARD, 0% [−2% to 1%]).

Gestational weight gain above guidelines was associated with higher risk of cesarean delivery (OR, 1.30 [95 CI, 1.25 to 1.35]; I^2 = 21.9%; ARD, 4% [95% CI, 3% to 6%]). The ARD was significant for underweight women only (underweight: OR, 1.45 [95% CI, 1.22 to 1.71]; ARD, 6% [95% CI, 1% to 12%]; normal weight: OR, 1.30 [95% CI, 1.24 to 1.36]; ARD, 0% [95% CI, −4% to 3%]; overweight: OR, 1.29 [95% CI, 1.21 to 1.39]; ARD, 1% [0% to 3%]; and obese: OR, 1.22 [95% CI, 1.05 to 1.42]; ARD, −2% [95% CI, −5% to 1%]).

Gestational Diabetes Mellitus

Six studies assessed GDM, but they did not use consistent definitions and had different findings for gestational weight gain above guidelines and GDM risk. Black et al[28] defined GDM by International Association of Diabetes in Pregnancy Study Groups criteria and included only women not treated for hyperglycemia (the center used different criteria in clinical practice and excluded those treated). They found no association between weight gain above guidelines and GDM in the underweight, normal-weight, and obese groups but reported lower risk in overweight women. Enomoto et al[22] used International Association of Diabetes in Pregnancy Study Groups criteria, with higher risk in normal-weight women and lower risk in overweight women. Durst et al[23] used Carpenter-Coustan criteria and found no association. Hung and Hsieh[24] used Carpenter-Coustan and International Association of Diabetes in Pregnancy Study Groups criteria and found an association of gestational weight gain above guidelines with lower risk of GDM in overweight and obese women. Li et al[36] included both impaired glucose tolerance and type 2 diabetes by WHO criteria, with weight gain above guidelines associated with lower risk of GDM in all groups except obese women. Shin and Song[31] used self-reported GDM and found an association of gestational weight gain above guidelines with lower risk in all groups except underweight women.

An intended meta-analysis of gestational weight gain and its relationship to GDM could not be completed because of inconsistent definitions and treatments.

Obese Subgroup Analysis Stratified by Obesity Class

Obesity classes include the following: class 1, BMI of 30 to 34.9; class 2, BMI of 35 to 39.9; and class 3, BMI of 40 or higher. Obese studies generally included a subgroup-defined weight loss as well as gestational weight gain below, within, or above guidelines. Three studies assessed outcomes stratified by BMI classes 1 through 3.[17,18,30] Another study[35] investigated only superobese women (BMI ≥50) and was included in the obesity class 3 analysis. These 4 studies were included in the subgroup analysis only (not in the overall meta-analyses). Class 1 included 67% of women; class 2, 22%; and class 3, 11%. Weight loss and gestational weight gain below, within, or above recommendations occurred in 6%, 13%, 25%, and 57% of pregnancies, respectively.

Figure 3 summarizes pooled ORs for primary (SGA and LGA) and secondary (macrosomia and cesarean delivery) outcomes. eFigure 3 in the Supplement shows pooled ORs for individual outcomes. eTable 4 in the Supplement reports ARDs and *P* values. Only 1 study[35] assessed preterm birth and GDM

Figure 3. Obese Subgroup Analysis With Summary of Pooled Odds Ratios (ORs) for the Association Between Gestational Weight Loss, Gain Below Guidelines, and Gain Above Guidelines With Adverse Outcomes

A Gestational weight loss

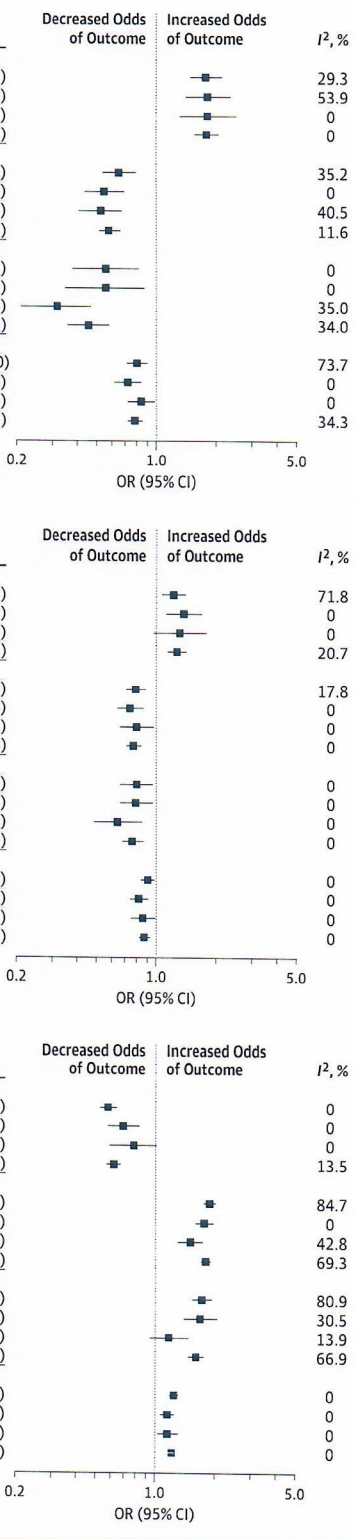
Outcomes by obesity class	Studies, No.	Women, No.	OR (95% CI)	I^2, %
SGA	3	85 668		
Class 1	3	2167	1.77 (1.48-2.13)	29.3
Class 2	3	1415	1.81 (1.40-2.35)	53.9
Class 3	3	1174	1.81 (1.31-2.50)	0
Overall			1.79 (1.56-2.05)	0
LGA	3	85 668		
Class 1	3	2167	0.65 (0.54-0.79)	35.2
Class 2	3	1415	0.55 (0.44-0.69)	0
Class 3	3	1174	0.53 (0.41-0.67)	40.5
Overall			0.58 (0.52-0.66)	11.6
Macrosomia	3	40 107		
Class 1	2	826	0.56 (0.38-0.81)	0
Class 2	2	617	0.56 (0.35-0.87)	0
Class 3	3	827	0.32 (0.21-0.47)	35.0
Overall			0.46 (0.36-0.58)	34.0
Cesarean delivery	4	86 702		
Class 1	3	2167	0.80 (0.71- 0.90)	73.7
Class 2	3	1415	0.72 (0.62-0.84)	0
Class 3	4	1344	0.84 (0.72-0.98)	0
Overall			0.78 (0.72-0.85)	34.3

B Gestational weight gain below guidelines

Outcomes by obesity class	Studies, No.	Women, No.	OR (95% CI)	I^2, %
SGA	3	85 668		
Class 1	3	6011	1.22 (1.07-1.40)	71.8
Class 2	3	3032	1.37 (1.12-1.69)	0
Class 3		1655	1.31 (0.97-1.78)	0
Overall			1.27 (1.14-1.41)	20.7
LGA	3	85 668		
Class 1	3	6011	0.79 (0.71-0.88)	17.8
Class 2	3	3032	0.74 (0.64-0.86)	0
Class 3	3	1655	0.80 (0.66-0.97)	0
Overall			0.77 (0.71-0.84)	0
Macrosomia	3	40 107		
Class 1	2	2906	0.80 (0.66-0.96)	0
Class 2	2	1566	0.79 (0.66-0.96)	0
Class 3	3	1265	0.64 (0.49-0.85)	0
Overall			0.76 (0.68-0.86)	0
Cesarean delivery	4	86 702		
Class 1	3	6011	0.91 (0.84-0.98)	0
Class 2	3	3032	0.82 (0.74-0.91)	0
Class 3	4	1881	0.86 (0.75-0.99)	0
Overall			0.87 (0.82-0.93)	0

C Gestational weight gain above guidelines

Outcomes by obesity class	Studies, No.	Women, No.	OR (95% CI)	I^2, %
SGA	3	85 668		
Class 1	3	35 489	0.58 (0.53-0.72)	0
Class 2	3	9627	0.69 (0.58-0.83)	0
Class 3	3	3629	0.78 (0.59-1.01)	0
Overall			0.62 (0.57-0.67)	13.5
LGA	3	85 668		
Class 1	3	35 489	1.87 (1.75-2.00)	84.7
Class 2	3	9627	1.76 (1.59-1.95)	0
Class 3	3	3629	1.50 (1.29-1.73)	42.8
Overall			1.79 (1.70-1.89)	69.3
Macrosomia	3	40 107		
Class 1	2	15 751	1.71 (1.53-1.92)	80.9
Class 2	2	4750	1.68 (1.39-2.04)	30.5
Class 3	3	2623	1.17 (0.94-1.46)	13.9
Overall			1.60 (1.46-1.75)	66.9
Cesarean delivery	4	86 702		
Class 1	3	35 489	1.24 (1.18-1.30)	0
Class 2	3	9627	1.15 (1.06-1.24)	0
Class 3	4	4024	1.15 (1.03-1.30)	0
Overall			1.21 (1.16-1.25)	0



Pooled ORs are shown for the association between gestational weight loss (A), gestational weight gain below guidelines (B), and gestational weight gain above guidelines (C) with adverse outcomes. Obesity classes indicate body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) as follows: class 1, BMI of 30 to 34.9; class 2, BMI of 35 to 39.9; and class 3, BMI of 40 or higher. Reference group is women with recommended weight gain in each category of BMI. For each outcome, the sample size represents the total number of women in the studies that assessed the outcome. For each obesity category, the sample size represents the total number of women with weight loss, gestational weight gain below the guidelines, or gestational weight gain above the guidelines.

in the obese subgroups, preventing meta-analysis. Kominiarek et al[18] provided separate ORs for nulliparous and multiparous women (multiparous values used herein), whereas other studies combined women with different parity into 1 group.

SGA by Obesity Class

Three studies assessed SGA. One defined SGA as birth weight less than the 10th percentile for gestational age alone,[18] and 2 also used sex and parity to define SGA.[17,30]

Weight loss and weight gain below guidelines were associated with higher SGA risk (weight loss: OR, 1.79 [95% CI, 1.56 to 2.05]; I^2 = 0%; ARD, 3% [95% CI, 1% to 5%]; weight gain below guidelines: OR, 1.27 [95% CI, 1.14 to 1.41]; I^2 = 20.7%; ARD, 1% [95% CI, 1% to 1%]). Gestational weight gain above guidelines was associated with lower SGA risk (OR, 0.62 [95% CI, 0.57 to 0.67]; I^2 = 13.5%; ARD, −1% [−2% to 0%]). Weight gain in class 1 had the strongest association with lower SGA risk (lowest OR, 0.58; 95% CI, 0.53 to 0.72]; *P* for trend < .001).

LGA by Obesity Class

Three studies assessed LGA. One defined LGA as birth weight greater than the 90th percentile for gestational age alone,[18] and 2 also used sex and parity to define LGA.[17,30]

Weight loss and gestational weight gain below guidelines were associated with lower LGA risk (weight loss: OR, 0.58 [95% CI, 0.52 to 0.66]; I^2 = 11.6%; ARD, −5% [95% CI, −7% to −3%]; weight gain below guidelines: OR, 0.77 [95% CI, 0.71 to 0.84]; I^2 = 0%; ARD, −2% [95% CI, −3% to −1%]). Weight loss in class 3 had the strongest association with lower LGA risk (lowest OR, 0.53 [95% CI, 0.41 to 0.67]; *P* for trend < .001). Weight gain above guidelines was associated with higher LGA risk (OR, 1.79 [95% CI, 1.70 to 1.89]; I^2 = 69.3%; ARD, 5% [95% CI, 5% to 6%]). LGA was most strongly associated with class 1 obesity compared with the other classes (highest OR, 1.87 [95% CI, 1.75 to 2.00]; *P* for trend < .001).

Macrosomia by Obesity Class

Three studies assessed macrosomia, defined as birth weight greater than 4000 g in 1 study,[30] greater than 4500 g in 1 study,[18] and both greater than 4000 g and greater than 4500 g in 1 study.[35] Meta-analysis used data for birth weight greater than 4000 g.

Weight loss and gestational weight gain below guidelines were associated with lower macrosomia risk (weight loss: OR, 0.46 [95% CI, 0.36 to 0.58]; I^2 = 34.0%; ARD, −5% [95% CI, −9% to −2%]; weight gain below guidelines: OR, 0.76 [95% CI, 0.68 to 0.86]; I^2 = 0%; ARD, −2% [95% CI, −3% to 0%]). Low weight gain in class 3 had the strongest association with lower macrosomia risk (lowest OR, 0.64 [95% CI, 0.49 to 0.85]; *P* for trend = .046). Gestational weight gain above guidelines was associated with higher risk of macrosomia (OR, 1.60 [95% CI, 1.46 to 1.75]; I^2 = 66.9%; ARD, 3% [95% CI, 0% to 6%]).

Cesarean Delivery by Obesity Class

Four studies assessed cesarean delivery. They included emergency,[30] emergency and elective,[18,35] and undefined[17] indications for cesarean delivery.

Weight loss and gestational weight gain below guidelines were associated with lower risk of cesarean delivery (weight loss: OR, 0.78 [95% CI, 0.72 to 0.85]; I^2 = 34.3%; ARD, −4% [95% CI, −6% to −3%]; weight gain below guidelines: OR, 0.87 [95% CI, 0.82 to 0.93]; I^2 = 0%; ARD, −2% [95% CI, −3% to −1%]). Gestational weight gain above guidelines was associated with higher risk of cesarean delivery (OR, 1.21 [95% CI, 1.16 to 1.25]; I^2 = 0%; ARD, 2% [95% CI, 0% to 3%]).

Metaregression

Substantial heterogeneity (I^2 > 50%) was present for gestational weight gain below and above guidelines for SGA, preterm birth, LGA, and macrosomia and for gestational weight gain above guidelines for cesarean delivery. When sufficient data were available, metaregression analysis was performed to investigate possible sources of heterogeneity: percentage of smokers during pregnancy, mean age, and percentage of nulliparous women (eTable 5 in the Supplement). The obese subgroups had insufficient studies to perform metaregression.

Gestational weight gain above guidelines and LGA demonstrated a source for heterogeneity (*P* = .04); specifically, there was an association between the treatment effect and the covariate smoking (*P* = .02). For gestational weight gain below guidelines and preterm birth, mean maternal age was the only covariate associated with outcome, where the risk for preterm birth varied by maternal age due to the heterogeneity in maternal age in included studies (*P* = .03); however, the overall *P* value was not significant (*P* = .09). Heterogeneity was unexplained for remaining outcomes.

Publication Bias

There was no evidence of publication bias for SGA, LGA, macrosomia or cesarean delivery (eFigure 4 in the Supplement). Assessment for publication bias was not performed for preterm births (<5 studies).

Risk of Bias

Participants were selected from maternity clinics or from large data sets (**Table 4**). Apart from 3 studies,[19,23,32] inclusion and exclusion criteria were adequately described. Performance bias (a potential difference in the care provided between BMI groups) was difficult to assess. Very few studies provided information regarding diet and/or exercise advice given and whether this differed between groups. Overweight and obese women were possibly treated more intensively, which could introduce bias.

Three studies demonstrated moderate bias risk[19,21,31] and 20 demonstrated low bias risk.[17,18,20,22-24,28-30,32-42] Reasons for moderate bias risk included self-reported final weight (detection bias), self-reported outcome measures (detection bias), failure to report all outcomes (report bias), and insufficient adjustment for confounding variables (confounding bias). Nineteen studies reported no conflict of interest.

Table 4. Summary of Risk of Bias Assessment

Source	Selection Bias, Exposed Cohort Representative	Detection Bias		Reporting Bias, Free of Selective Outcome Reporting	Assessment of Confounding in Original Analysis	Conflict of Interest	Overall Risk of Bias
		Adequate Exposure Measures	Adequate Outcome Measures				
Durst et al,[23] 2016	Yes	Yes	Yes	Yes	Yes	No	Low
Enomoto et al,[22] 2016	Yes	NR	Yes	Yes	Yes	No	Low
Hung and Hsieh,[24] 2016	Yes	Yes	Yes	Yes	Yes	No	Low
Xiong et al,[29] 2016	Yes	Yes	Yes	Yes	Yes	No	Low
Bogaerts et al,[30] 2015	Yes	Yes	Yes	Yes	Yes	No	Low
Shin and Song,[31] 2015	Yes	Yes	No (self-reported)	Yes	Partial (did not adjust for parity)	No	Moderate
Wen and Lv,[21] 2015	NR	Yes	NR	Partial (not all outcomes reported)	Partial (did not adjust for required number of confounders)	No	Moderate
Yang et al,[32] 2015	Yes	Yes	Yes	Yes	Yes	No	Low
Badon et al,[20] 2014	Yes	Yes	Yes	Yes	Yes	No	Low
Chihara et al,[19] 2014	Yes	Partial (self-reported final weight)	No (self-reported)	Yes	Yes	NR	Moderate
Haugen et al,[33] 2014	Yes	Partial (self-reported final weight)	Yes	Yes	Yes	No	Low
Lee et al,[34] 2014	NR	Yes	Yes	Yes	Yes	No	Low
Swank et al,[35] 2014	Yes	Yes	Yes	Yes	Yes	No	Low
Black et al,[28] 2013	Yes	Yes	Yes	Yes	Yes	No	Low
Kominiarek et al,[18] 2013	Yes	Yes	Yes	Yes	Yes	No	Low
Li et al,[36] 2013	Yes	Yes	Yes	Yes	Yes	No	Low
Di Benedetto et al,[37] 2012	Yes	Yes	Yes	Yes	Partial (did not adjust for parity)	No	Low
Simas et al,[38] 2012	Yes	Partial (some self-reported final weight)	Yes	Yes	Yes	No	Low
Blomberg,[17] 2011	Yes	Yes	Yes	Yes	Yes	No	Low
Park et al,[39] 2011	Yes	Yes	Yes	Partial (not all outcomes reported)	Yes	NR	Low
Park et al,[40] 2011	Partial	NR	Yes	Yes	Yes	NR	Low
Vesco et al,[41] 2011	Yes	Yes	Yes	Yes	Yes	No	Low
Rode et al,[42] 2007	NR	Partial (self-reported final weight)	Yes	Yes	Partial (did not adjust for parity)	NR	Low

Abbreviation: NR, not reported.

Discussion

In this analysis of 1 309 136 pregnancies from diverse international cohorts, gestational weight gain below or above 2009 IOM guidelines among women across the BMI range was associated with greater risk for maternal and infant adverse outcomes. Underweight women composed 7%; normal-weight women, 55%; overweight women, 18%; and obese women, 20%. For gestational weight gain, 23% gained below and 47% gained above guidelines. Compared with recommended gestational weight gain, gain below guidelines was associated with 5% higher risk of both SGA and preterm birth and 2% lower risk of both LGA and macrosomia. Weight gain above guidelines was associated with 3% lower risk of SGA and 2% lower risk of preterm birth and 4%, 6%, and 4% higher risk of LGA, macrosomia, and cesarean delivery, respectively.

Gestational weight gain below guidelines was associated with higher SGA risk, with greatest risk in underweight women, as shown previously.[43,44] Obesity was associated with higher risk of SGA, with weight loss and gestational weight gain below guidelines increasing risks, similar to prior systematic reviews.[26,45,46] Underweight status combined with gestational weight gain below recommendations as well as obese status combined with gestational weight loss present the highest risk groups for SGA, at 8% and 3%, respectively.

Gestational weight gain below guidelines was associated with a 5% increase in preterm birth across the included populations. With 23% having weight gain below recommendations, this could correspond to 15 000 more preterm birth events. Weight gain above guidelines was associated with lower risk of preterm birth. Prior reviews have shown similar associations, but they did not stratify by prepregnancy BMI and gestational weight gain.[47,48] One small systematic review in obese

women did not find associations between preterm birth and weight gain outside guidelines.[49] With larger sample sizes and stratification by BMI and prepregnancy weight gain, the current review adds to prior work and has greater clinical applicability. Also, as maternal BMI increased, the association between gestational weight gain below guidelines and preterm birth risk was weakened, consistent with an earlier review.[3]

Gestational weight gain below guidelines was associated with lower risks of LGA and macrosomia. This association was lowest in underweight women. Weight gain above guidelines was associated with higher risks of LGA and macrosomia, with ARDs of 4% and 6% greater risks, respectively. Underweight status was associated with the greatest risk. This is similar to the 2009 IOM report[6] that stated, "the lower the prepregnancy BMI, the stronger the association between increased gestational weight gain and birthweight"; it may be related to higher absolute weight gain in underweight women.[1] Animal studies suggest that baseline maternal BMI and gestational weight gain are associated with changes in the hormonal milieu, including insulin resistance.[50] Similarly, excess weight gain in underweight women may be associated with greater changes in the hormonal milieu and placental function than in normal-weight or overweight women. Weight gain above guidelines was associated with increased risk of cesarean delivery across the BMI spectrum.

Similarly, within the obese subgroups, weight loss was associated with a 5% lower risk for both LGA and macrosomia and 4% lower risk for cesarean delivery. Weight gain below guidelines was associated with 2% lower risk across all these outcomes. Class 3 obesity combined with weight loss was associated with the greatest LGA risk reduction. Gestational weight gain above guidelines was associated with increased LGA risk. Class 1 obesity was associated with the greatest risk for LGA, which may be partly due to higher absolute weight gain in less obese women.[10] While other systematic reviews have assessed gestational weight gain below guidelines,[26] to our knowledge, this is the first review exploring relationships between weight gain above guidelines and outcomes within obesity classes.

While GDM has adverse maternal and infant outcomes[51] and is related to maternal BMI and possibly to gestational weight gain, associations could not be assessed because of heterogeneity of diagnosis and treatment as well as the potential effect of GDM treatment on gestational weight gain. Prior systematic reviews have not demonstrated that healthy lifestyle and gestational weight gain reduced rates of GDM,[14] even in high-risk populations.[52] Consistent diagnostic criteria and reporting of gestational weight gain at GDM diagnosis are needed to study associations between gestational weight gain and GDM.

Lifestyle interventions in pregnancy can help women attain recommended gestational weight gain.[14] Optimal interventions and effects on outcomes are currently being studied in a large-scale international individual patient data meta-analysis.[53] The WHO has prioritized achievement of ideal BMI prior to conception and prevention of excess gestational weight gain.[54] Identification of women prior to conception and implementing healthy lifestyle strategies before and during pregnancy have yet to be integrated into routine health care,[55] requiring research implementation.

Strengths of this review are the inclusion of common maternal and infant risks associated with gestational weight gain below and above the 2009 IOM guidelines in women across the prepregnancy BMI spectrum and across international cohorts. Four databases were searched, a risk of bias appraisal was performed, and reanalyses were undertaken, allowing inclusion of data from more than 1.3 million pregnant women globally. Collaboration with other authors facilitated more homogeneous data, data integration, and meta-analysis.

Limitations

This study has limitations. It lacks studies from developing countries and excluded non-English-language articles. Fifteen of 31 authors contacted were unable to reanalyze data, so these studies were excluded from the meta-analysis. A meta-analysis could not be performed for GDM because of inconsistent primary data. Some outcomes were assessed in only 1 study, precluding meta-analysis. Inconsistent definitions of preterm birth, cesarean delivery, and macrosomia limited interpretation of findings. Study heterogeneity may have affected reliability of results, although the metaregression did not identify characteristics responsible for this heterogeneity. Studies published before 2009 IOM guidelines were included, and gestational weight gain targets before and after these guidelines may have differed. Preterm birth was not adjusted for gestational age, potentially resulting in less total gestational weight gain than would have been otherwise attained. Spontaneous and induced preterm birth were not clearly differentiated, and studies did not distinguish between emergency and elective or primary and repeated cesarean deliveries. These factors may limit interpretation and underscore the importance of improving outcome definition reporting. Event rates were not available for all studies, limiting interpretation of ARDs. Findings from this review are based on observational data and no causal links may be concluded. They may be applicable on a population level, but recommendations need to be individualized when applied clinically.

Conclusions

In this systematic review and meta-analysis of more than 1 million pregnant women, 47% had gestational weight gain greater than IOM recommendations and 23% had gestational weight gain less than IOM recommendations. Gestational weight gain greater than or less than guideline recommendations, compared with gestational weight gain within recommended levels, was associated with higher risk of adverse maternal and infant outcomes.

ARTICLE INFORMATION

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Author Contributions: Dr Goldstein and Mr Ranasinha had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
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Acquisition, analysis, or interpretation of data: Goldstein, Abell, Ranasinha, Boyle, Black, Li, Hu, Corrado, Rode, Y. J. Kim, Haugen, Song, M. H. Kim, Bogaerts, Devlieger, Chung, Teede.
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2.3 Gestational weight gain across continents and ethnicity: Systematic review and meta-analysis of maternal and infant weight outcomes in more than one million women

Goldstein RF, Abell SK, Ranasinha S, Misso ML, Boyle JA, Harrison CL, Black MH, Li N, Hu G, Corrado F, Hegaard H, Kim YJ, Haugen M, Song WO, Kim MH, Bogaerts A, Devlieger R, Chung JH, Teede HJ.

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Gestational weight gain across continents and ethnicity: systematic review and meta-analysis of maternal and infant outcomes in more than one million women

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Abstract

Background: The association between Institute of Medicine (IOM) guidelines and pregnancy outcomes across ethnicities is uncertain. We evaluated the associations of gestational weight gain (GWG) outside 2009 IOM guidelines, with maternal and infant outcomes across the USA, western Europe and east Asia, with subgroup analyses in Asia. The aim was to explore ethnic differences in maternal prepregnancy body mass index (BMI), GWG and health outcomes across these regions.

Methods: Systematic review, meta-analysis and meta-regression of observational studies were used for the study. MEDLINE, MEDLINE In-Process, Embase and all Evidence-Based Medicine (EBM) Reviews were searched from 1999 to 2017. Studies were stratified by prepregnancy BMI category and total pregnancy GWG. Odds ratio (ORs) 95% confidence intervals (CI) applied recommended GWG within each BMI category as the reference. Primary outcomes were small for gestational age (SGA), preterm birth and large for gestational age (LGA). Secondary outcomes were macrosomia, caesarean section and gestational diabetes.

Results: Overall, 5874 studies were identified and 23 were included (n = 1,309,136). Prepregnancy overweight/obesity in the USA, Europe and Asia was measured at 42%, 30% and 10% respectively, with underweight 5%, 3% and 17%. GWG below guidelines in the USA, Europe and Asia was 21%, 18% and 31%, and above was 51%, 51% and 37% respectively. Applying regional BMI categories in Asia showed GWG above guidelines (51%) was similar to that in the USA and Europe.

GWG below guidelines was associated with a higher risk of SGA (USA/Europe [OR 1.51; CI 1.39, 1.63]; Asia [1.63; 1.45, 1.82]) and preterm birth (USA/Europe [1.35; 1.17, 1.56]; Asia [1.06; 0.78, 1.44]) than GWG within guidelines. GWG above guidelines was associated with a higher risk of LGA (USA/Europe [1.93; 1.81, 2.06]; Asia [1.68; 1.51 , 1.87]), macrosomia (USA/Europe [1.87; 1.70, 2.06]; Asia [2.18; 1.91, 2.49]) and caesarean (USA/Europe [1.26; 1.21, 1.33]; Asia [1.37; 1.30, 1.45]). Risks remained elevated when regional BMI categories were applied for GWG recommendations. More women in Asia were categorised

(Continued on next page)

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as having GWG below guidelines using World Health Organization (WHO) (60%) compared to regional BMI categories (16%), yet WHO BMI was not accompanied by increased risks of adverse outcomes.

Conclusions: Women in the USA and western Europe have higher prepregnancy BMI and higher rates of GWG above guidelines than women in east Asia. However, when using regional BMI categories in east Asia, rates of GWG above guidelines are similar across the three continents. GWG outside guidelines is associated with adverse outcomes across all regions. If regional BMI categories are used in east Asia, IOM guidelines are applicable in the USA, western Europe and east Asia.

Keywords: Pregnancy, Ggestational weight gain, Maternal and infant outcomes, Obesity, Small for gestational age, Large for gestational age, Gestational diabetes, Caesarean section, Macrosomia, Preterm birth

Background

Gestational weight gain (GWG) is influenced by many factors including the obesogenic environment, prepregnancy body mass index (BMI), age, parity, smoking, socioeconomic status and comorbid medical conditions [1, 2]. Excess or insufficient GWG is associated with higher risks of adverse pregnancy outcomes, including preterm birth, macrosomia and caesarean delivery [3]. The US Institute of Medicine (IOM) developed GWG guidelines in 1990 and updated them in 2009 (Table 1), yet nearly three quarters of women now gain weight outside these guidelines [4, 5]. Given that lifestyle intervention improves outcomes, meeting GWG guidelines is an important target [6]. However, the IOM guidelines are based on data from primarily USA-dwelling, Caucasian and Black women, with limited ethnic diversity that may not be applicable to women from Europe and Asia. Given that Asia is the most populous continent, inhabited by 60% of the world's population, applicability of GWG guidelines to Asian populations is an international public health priority.

At lower BMI, people from Asia have a greater risk for cardiovascular disease and diabetes [7, 8] than Caucasians, with a higher body fat percentage and greater central obesity [9]. During pregnancy, women from Asian countries have different risk profiles than Caucasian women. Asian-American women have a higher risk of gestational diabetes mellitus (GDM), caesarean section and low birthweight babies, and a lower risk of gestational hypertension and macrosomia compared to non-Hispanic white women [10]. Amongst Asian women, Korean and Taiwanese women have greater GWG and postpartum weight retention than women from other Asian countries [11]. In this context, GWG guidelines in Asian women may need to be considered differently; however, there is insufficient comparative research to date.

The 2009 IOM guidelines, although based on limited data, showed no ethnic differences in associations between GWG and pregnancy outcomes, whilst calling for further research [4]. Currently, there are no specific GWG guidelines for women from Asia. Most Asian studies use Caucasian-derived IOM GWG guidelines, and some use their own regional guidelines [12]. This creates heterogeneity and limits comparisons across regions, underpinning calls for new ethnic-specific regional GWG guidelines in China [13], highlighting gaps in current guidelines.

In this systematic review, meta-analysis and meta-regression, we aimed to explore ethnic differences in maternal prepregnancy BMI, GWG and health outcomes across the USA, Europe and Asia. In Asia, we also aimed to explore GWG and health outcomes using ethnic-specific regional BMI and World Health Organization (WHO) BMI categories.

Methods

This systematic review and meta-analysis was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) protocol. This protocol was registered with the PROSPERO International Prospective Register of Systematic reviews (registration number CRD42015023325). An analysis of all pooled data is published [5]. This study focused on ethnic differences in maternal BMI, GWG and maternal and neonatal outcomes.

The methods used for study eligibility, data extraction and risk of bias have been detailed previously [5] (search

Table 1 2009 IOM Recommendations for gestational weight gain during pregnancy

Recommendations	Underweight	Normal weight	Overweight	Obese
Prepregnancy BMI (kg/m^2)	< 18.5	18.5–24.9	25.0–29.9	≥30
Total weight gain range (kg)	12.5–18	11.5–16	7–11.5	5–9
Total weight gain range (lbs)	28–40	25–35	15–24	11–20

Adapted from 2009 IOM guidelines

terms and search strategy are discussed in Additional files 1 and 2). Briefly, observational studies published in the English language between January 1999 and February 2017, with a sample size of more than 500 women were included. Studies assessing multiple pregnancies and pregnancies in women < 18 years were excluded. Inclusion required that studies present data examining the women by prepregnancy BMI category (underweight, normal weight, overweight, obese), stratified by the total pregnancy GWG (studies using weekly GWG were excluded). The odds ratio (OR) for each outcome had to be stratified by maternal BMI and GWG. Papers that mutually adjusted for BMI and GWG were excluded.

After identifying wide variations in prepregnancy BMI and GWG categories, meaningful interpretation and meta-analysis were not possible. Relevant authors were contacted to reanalyse and present data using consistent categories. Chinese and Korean studies used ethnic-specific BMI categories (China: underweight BMI < 18.5 kg/m^2, normal weight 18.5–23.9 kg/m^2, overweight 24–28 kg/m^2 and obese ≥ 28 kg/m^2; Korea: underweight BMI < 18.5 kg/m^2, normal weight 18.5–22.9 kg/m^2, overweight 23–25 kg/m^2 and obese ≥ 25 kg/m^2) whilst Japanese and Taiwanese studies used WHO BMI categories (underweight < 18.5 kg/m^2, normal weight 18.5–24.9 kg/m^2, overweight 25–29.9 kg/m^2 and obese ≥30 kg/m^2).

Primary outcomes were (1) small for gestational age (SGA): < 10th percentile of birthweight for sex and gestational age, (2) pre-term birth: spontaneous birth < 37 weeks gestation, (3) large for gestational age (LGA): > 90th percentile of birthweight for sex and gestational age. Secondary outcomes were (1) macrosomia: birthweight > 4000 g, (2) caesarean section and (3) GDM.

Strategy for data synthesis

Study findings were synthesised based on target population characteristics, type of study and outcome. Proportions were calculated using the pooled number in a group divided by the total number (%). The chi-squared test was used to assess difference in proportion of women within BMI categories and GWG categories between regions. The two-sample test of proportions was used to assess differences between two particular regions.

Summaries of outcomes associated with GWG were produced for each study by calculating the ORs and 95% confidence intervals (CIs), using the recommended GWG within each BMI category as the reference. Where two or more studies assessed the same outcome, the results were pooled using random-effects meta-analysis, calculating the OR and 95% CI for each outcome. Extracted pooled ORs for each outcome were combined to construct a summary pooled OR for all outcomes. Crude data was used where possible given the variation in control for confounding factors. However, some papers presented adjusted ORs only [14–21]. US and European studies were combined as one group in the meta-analysis of pregnancy outcomes (to allow for two or more studies to assess each outcome) and compared to Asian studies. We were unable to demonstrate statistical significance for comparison of ORs for SGA, preterm birth, LGA, macrosomia and caesarean section between the US/Europe and Asian studies due to similar ORs and overlap in CIs.

Heterogeneity was assessed using the I^2 statistic. An I^2 value greater than 50% was indicative of substantial heterogeneity [22] . Where there was sufficient data available, a meta-regression analysis was performed to investigate sources of heterogeneity, including percentage of smokers in pregnancy, mean age and percentage nulliparity. Sufficient data on race/ethnicity was not available for inclusion in the meta-regression. Studies from Europe and Asia did not provide information regarding race or ethnicity. Studies from the USA provided race/ethnicity data; however, this varied with reporting methods (some report percentage of total population, others report percentage stratified by GWG).

A further analysis of women living in Asian countries was performed comparing studies using regional BMI categories (Chinese and Korean studies) and WHO BMI categories (Japanese and Taiwanese) assessing alignment with 2009 IOM GWG guidelines and maternal and infant adverse outcomes. Statistical analysis used Stata software v.14 and was supported by a biostatistician (SR).

Results

From 5874 studies identified by the initial search, 302 studies were selected for full text review (Fig. 1) and 261 studies were excluded, using a priori selection criteria. Forty papers grouped women by prepregnancy BMI category (underweight, normal weight, overweight, obese), stratified by the total GWG for the pregnancy. One study [23] did not initially meet inclusion criteria because ORs were not stratified by both BMI and GWG. However, through collaborations, this data was available in the required format. Where required, authors were contacted for data reanalysis, and 13 collaborated (Additional file 2).

In total, 23 cohort studies [12, 14–21, 23–36] were included in this systematic review and meta-analysis, reporting data on more than 1 million women (n = 1,309,136).

Study characteristics

Table 2 describes the study design and size, eligibility criteria and outcomes (descriptive characteristics are shown in Additional file 3: Table S1). Eighteen studies were retrospective, five were prospective [14, 25, 28, 31, 36]. Ten studies were from the USA [14, 17, 18, 20, 23, 27, 29, 30,

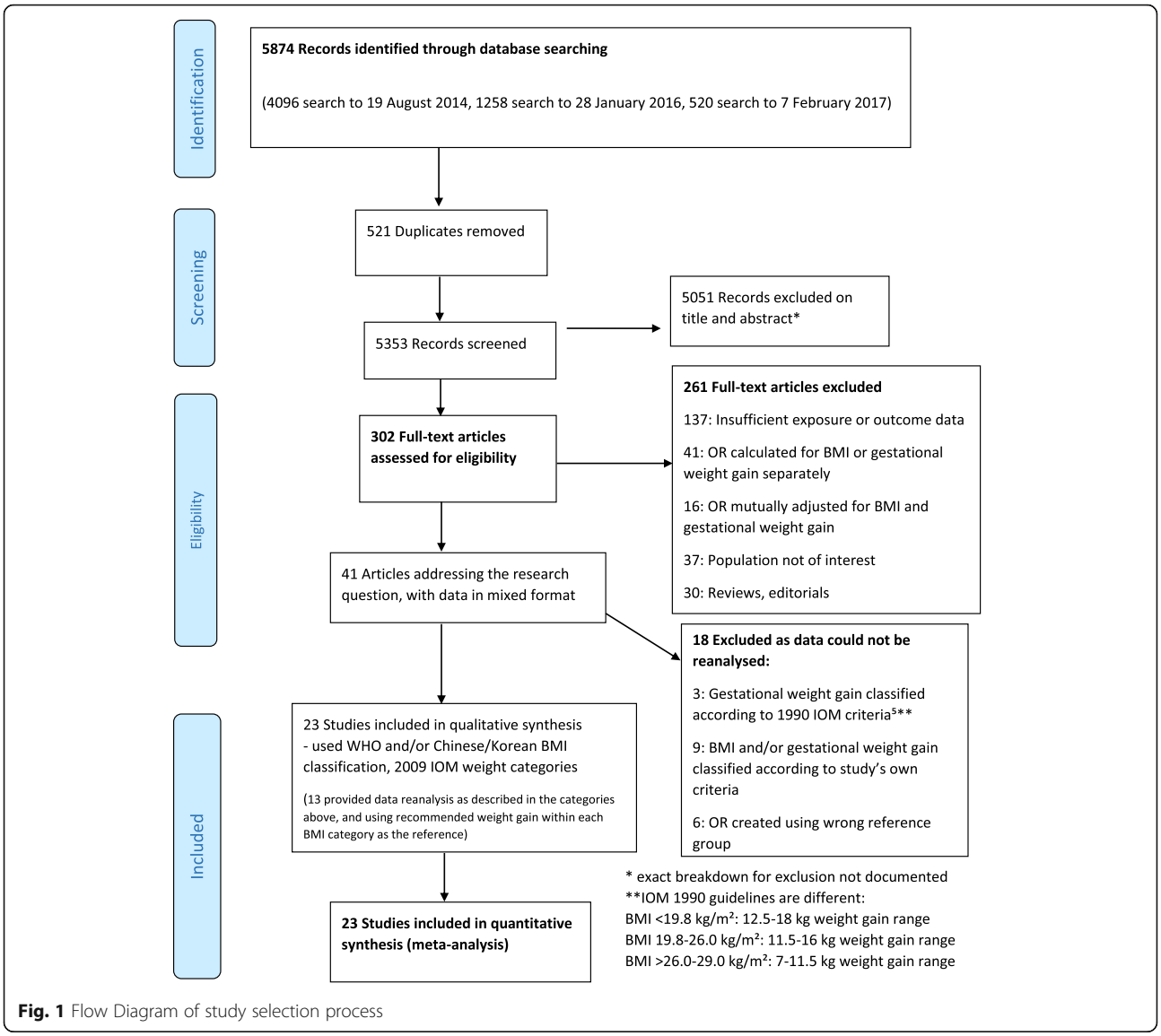

Fig. 1 Flow Diagram of study selection process

32, 33], five from western Europe (one each from Norway [25], Belgium [35], Italy [24], Denmark [28] and Sweden [15]) and eight from east Asia (four from China [16, 26, 31, 36], two from Korea [12, 34], one each from Taiwan [21] and Japan [19]). The sample size ranged from 1034 to 570,672.

Overall, 66% ($n = 865{,}790$) of women were from the USA, 10% ($n = 125{,}203$) from Western Europe and 24% ($n = 318{,}143$) from east Asia.

Analysis by region: USA, Europe and Asia

In the descriptive analysis of maternal BMI only, it was required to exclude two European studies [15, 35] (52% of European women) and four US studies [18, 20, 30, 32] (3% of US women) which studied obese women only, and one Asian study [16] (4% of Asian women) which studied normal weight women only. In the remaining studies, overweight and obesity were present in 43% of women in the USA, 31% in Europe and 10% in Asia (Table 3). Underweight BMI was present in 5% in the USA, 3% in Europe and 17% in Asia. The proportion of women within each BMI category was different between the regions ($p < 0.0001$) (using the chi-squared test).

Overall, underweight women had the greatest prevalence of GWG below guidelines (43%), whereas overweight women, followed by obese women, had the greatest prevalence of GWG above guidelines (64% and 60% respectively) (Table 4).

For GWG below guidelines, prevalence was 21%, 18% and 31% in the USA, Europe and Asia respectively, including all Asian data (Table 5). The proportion of women gaining below guidelines was different between the three regions ($p < 0.0001$) (using the chi-squared test).

Table 2 Characteristics of 23 included studies

Study	Country	Study period	Study design	Sample size	Setting	Outcomes
Durst, 2016 [20]	USA	2000–2014	Retrospective	5651	University of Alabama, Birmingham	SGA, LGA, macrosomia, caesarean section
Enomoto, 2016 [19]	Japan	2013	Retrospective	97,157	Japan Society of Obstetrics and Gynaecology Registry system with 280 participating hospitals	SGA, preterm birth, LGA, macrosomia, caesarean
Hung, 2016 [21]	Taiwan	2009–2015	Retrospective	10,973	Taipei Chang Gung Memorial Hospital	SGA, LGA, macrosomia, caesarean section
Xiong[e], 2016 [36]	China	2012–2013	Prospective	57,891	Hospitals and community centres	Caesarean section
Bogaerts, 2015 [35]	Belgium	2009–2011	Retrospective	18,053	Flemish study center for perinatal	Caesarean section, macrosomia, LGA
Shin, 2015 [33]	USA	2004–2011	Retrospective	219,868	Pregnancy risk assessment monitoring system (PRAMS)	Preterm birth, SGA, LGA
Wen[e], 2015 [16]	China	2009–2013	Retrospective	13,776	Jishuitan Hospital	Preterm birth
Yang[e], 2015 [31]	China	2011–2013	Prospective	85,765	Wuhan Women and Children Health Care Center	Macrosomia
Badon, 2014 [14]	USA	2000–2006	Prospective	5297	North American Field Centers, HAPO	LGA
Chihara, 2014 [17]	USA	2003–2005	Retrospective	19,130	Hawaii's special supplemental program for women, infants and children (WIC)	Macrosomia
Haugen[c], 2014 [25]	Norway	1999–2008	Prospective	56,082	Norwegian Mother and Child cohort study	Macrosomia, caesarean section
Lee[d], 2014 [34]	Korea	2010–2012	Retrospective	16,297	Single medical centre	LGA
Swank, 2014 [32]	USA	2007	Retrospective	1034	Californian birth certificate data	Caesarean, macrosomia
Black, 2013 [23]	USA	2005–2010	Retrospective	9835	Kaiser Permanente Southern California	LGA (provided additional outcomes in reanalysis incl. SGA, preterm, macrosomia and caesarean section
Kominiarek[b], 2013 [18]	USA	2002–2008	Retrospective	21,020	12 institutions (19 hospitals)	Caesarean section, SGA, LGA, macrosomia
Li[a], 2013 [26]	China	2009–2011	Retrospective	33,973	Tianjin Women's and Children's Health Centre	Caesarean, preterm delivery, LGA, SGA macrosomia
Di Benedetto, 2012 [24]	Italy	2004–2009	Retrospective	2225	University Hospital	Macrosomia, caesarean section
Moore Simas, 2012 [29]	USA	2006–2010	Retrospective	11,203	University Hospital	SGA, LGA
Blomberg, 2011 [15]	Sweden	1993–2008	Retrospective	46,595	Swedish Medical birth registry	Caesarean, LGA, SGA
J Park[d], 2011 [12]	Korea	2005–2007	Retrospective	2311	University Hospital	SGA, LGA, macrosomia, caesarean section, preterm birth
S Park, 2011 [27]	USA	2004–2007	Retrospective	570,672	Florida birth certificate data	SGA, LGA
Vesco, 2011 [30]	USA	2000–2005	Retrospective	2080	Kaiser Permanente group practice	Macrosomia, LGA, SGA
Rode, 2007 [28]	Denmark	1996–1998	Prospective	2248	University Hospital	Macrosomia

[a]Data according to both Chinese and WHO BMI categories (Chinese used here)
[b]Sample size changed when provided additional data, OR not recalculated
[c]Sample size changed when provided additional data
[d]Data according to both Korean and WHO BMI categories (Korean used here)
[e]Data according to Chinese BMI categories
HAPO Hyperglycaemia and Adverse Pregnancy Outcomes, *NR* not reported

Table 3 Body mass index prepregnancy by regions (%)

Region	Underweight	Normal weight	Overweight	Obese
Including all studies				
USA	5	51	23	21
Europe	1	33	10	6
Asia	16	74	8	2
Excluding studies that assessed obese women [15, 18, 20, 30, 32, 35] or normal weight women only [16]				
USA	5	53	24	18
Europe	3	67	21	9
Asia (overall)	17	73	8	2
Asia (regional BMI)	16	73	9	2
Asia (WHO BMI)	18	71	8	3

For GWG above guidelines, prevalence was 51%, 51% and 37% in the USA, Europe and Asia respectively, including all Asian data. The proportion of women above guidelines was different between the three regions ($p <$ 0·0001) (using the chi-squared test). GWG above guidelines was higher in the USA than Asia ($p < 0·0001$) and higher in Europe than Asia ($p < 0·0001$), but this was not true between the USA and Europe ($p = 1·0$) (using the two-sample test of proportions).

However, when Asian studies applying regional BMI categories only were analysed, GWG above guidelines (51%) was no longer significantly different from GWG above guidelines in the USA and Europe ($p = 0.28$). There was a substantial difference between GWG below guidelines in Asia, using regional BMI (16%), compared to WHO BMI categories when applying IOM guidelines (60%).

A summary of pooled ORs for primary and secondary outcomes is given in Fig. 2a and b and Table 6. Pooled ORs for individual analyses for outcomes are presented in Additional file 4.

Primary outcomes

SGA: eleven studies (seven USA/Europe; four Asia) Eleven studies assessed SGA. This was defined as birthweight < 10th percentile for gestational age in five studies [12, 19, 26, 27, 33]; four additionally accounted for sex [21, 23, 25, 29], one for sex and race/ethnicity [30] and another for sex, race and parity [20].

Table 4 Proportions of women gaining below, within and above guidelines, stratified by prepregnancy BMI (%)

BMI group	Below IOM	Within IOM	Above IOM
Underweight	43	36	21
Normal weight	28	36	36
Overweight	13	23	64
Obese	19	21	60

Data from 20/23 studies: $n = 1{,}146{,}350$ (88% of total population). Excluding studies that did not stratify GWG by BMI category [17, 31, 36]

GWG below guidelines was associated with a higher risk for SGA than GWG within guidelines; for USA/Europe OR 1.51 (1.39–1.63), $I^2 = 88\%$ and for Asia OR 1.63 (1.45–1.82), $I^2 = 63$. The association of SGA risk was highest with underweight women for both USA/Europe (1.95; 1.83–2.07) and Asia (1.90; 1.34–2.70).

GWG above guidelines was associated with lower risk for SGA than GWG within guidelines: USA/Europe (OR 0.65; 0.62–0.69) $I^2 = 65\%$ and Asia (OR 0.69; 0.63–0.76) $I^2 = 20\%$.

Preterm birth: five studies (two USA/Europe; three Asia) Five studies assessed preterm birth (< 37 weeks gestation); four did not specify whether this was spontaneous or induced [16, 23, 26, 33] and one specified spontaneous and induced combined [19].

GWG below guidelines was associated with a higher risk for preterm birth than GWG within guidelines: USA/Europe (OR 1.35; 1.17–1.56) $I^2 = 81\%$ and Asia (OR 1.06; 0.78–1.44) $I^2 = 86\%$.

GWG above guidelines was associated with a lower risk for preterm birth than GWG within guidelines: USA/Europe (0.83; 0.74–0.94) $I^2 = 79\%$ and Asia (OR 0.71; 0.58–0.87) $I^2 = 68\%$.

LGA: thirteen studies (eight USA/Europe; five Asia) Thirteen studies assessed LGA. This was defined as birthweight > 90th percentile for gestational age in six studies [12, 19, 26, 27, 33, 34]. Four defined LGA by additionally accounting for infant sex [21, 23, 25, 29], one for sex and race/ethnicity [30], one for sex, race and parity [20] and one for sex, parity and study centre [14].

GWG below guidelines was associated with a lower risk for LGA than GWG within guidelines: USA/Europe (OR 0.62; 0.57–0.68) $I^2 = 72\%$ and Asia (OR 0.55; 0.48–0.63) $I^2 = 78\%$. The risk was lowest in the underweight women: (USA/Europe [OR 0.42; 0.30–0.60] and Asia [OR 0.42; 0.30–0.59]).

GWG above guidelines was associated with a higher risk for LGA: USA/Europe (OR 1.93; 1.81–2.06) $I^2 =$

Table 5 Gestational weight gain during pregnancy by regions (%)

Region	Below guidelines	Within guidelines	Above guidelines
Including all studies			
USA	21	28	51
Europe	18	31	51
Asia (overall)	31	32	37
Asia (regional BMI)	16	33	51
Asia (WHO BMI)	60	31	9

Including all studies

80% and Asia (OR 1.68; 1.51–1.87) I^2 = 69%. For both groups, the risk was greatest in underweight women, with risk decreasing as BMI increased.

Secondary outcomes

Macrosomia: twelve studies (seven USA/Europe; five Asia) Macrosomia was defined as birthweight > 4000 g in the majority [12, 17, 19–21, 23–26, 28, 31]; one study used birthweight > 4500 g [30].

GWG below guidelines was associated with a lower risk for macrosomia than GWG within guidelines: USA/Europe (OR 0.62; 0.54–0.70) I^2 = 39% and Asia (OR 0.60; 0.47–0.77) I^2 = 79%.

GWG above guidelines was associated with a higher risk for macrosomia: USA/Europe (OR 1.87; 1.70–2.06) I^2 = 56% and Asia (OR 2.18; 1.91–2.49) I^2 = 66%. In Asia, the risk decreased as the BMI increased.

Caesarean section: nine studies (four USA/Europe; five Asia) Nine studies assessed caesarean section. Seven included emergency and elective deliveries [12, 19, 23–26, 36] and two did not specify [20, 21]. Two [20, 23] included repeat caesarean (total caesarean section), one primary caesarean only [21] and six did not distinguish these.

GWG below guidelines was associated with a lower risk for caesarean: USA/Europe (OR 0.92; 0.87–0.98) I^2 = 0%, with no statistically significant result for Asia (OR 0.98; 0.89–1.06) I^2 = 83%.

GWG above guidelines was associated with a higher risk for caesarean: USA/Europe (OR 1.26; 1.21–1.33) I^2 = 0% and Asia (OR 1.37; 1.30–1.45) I^2 = 59%. In Asia, the risk was greatest in underweight women (OR 1.51; 1.30–1.45).

Gestational diabetes: Six studies Six studies assessed GDM, but did not use consistent definitions, and had different findings for GWG above guidelines and GDM risk, preventing the intended meta-analysis of GDM and its relationship to GWG.

We were unable to demonstrate statistical significance for comparison of ORs for SGA, preterm birth, LGA, macrosomia and caesarean section between the USA/Europe and Asian studies due to similar ORs and overlap in CIs.

Subgroup analysis: Asian studies

Of the eight studies from Asia, four were from China [16, 26, 31, 36], two from Korea [12, 34], with one each from Japan [19] and Taiwan [21].

Results are stratified by country in Additional files 5 and 6 (Table S2: BMI at onset of pregnancy and Table S3: GWG during pregnancy).

Comparison between studies using ethnic-specific regional BMI categories and WHO BMI categories

A further analysis comparing studies using regional BMI categories (Chinese and Korean studies) and WHO BMI categories (Japanese and Taiwanese studies) was performed to assess for differences in adherence to 2009 IOM GWG guidelines and differences in maternal and infant adverse outcomes.

Asian studies using ethnic-specific regional BMI categories showed 16% of women with GWG below guidelines, 33% within and 51% above, whereas studies using WHO BMI categories had 60% with GWG below, 31% within and 9% above (Table 5).

An additional meta-analysis was performed in Asian studies, where studies using regional BMI categories (Chinese and Korean studies) were compared to those studies using WHO BMI categories (Japanese and Taiwanese studies) (Table 6). Pooled ORs for individual analyses for outcomes are presented in Additional file 7.

SGA, LGA, macrosomia and caesarean section could be examined in a meta-analysis (Table 6).

Wen et al. only included normal weight women, and Yang et al. had women in all weight categories except obese. Yang defined underweight as < 18 kg/m^2.

For OR calculation, Hung, Xiong and Yang combined overweight and obese into one group. The OR was used for the overweight group here. Although Enomoto created separate ORs for overweight and obese, only overweight was used in the meta-analysis as there were no comparison groups for obese.

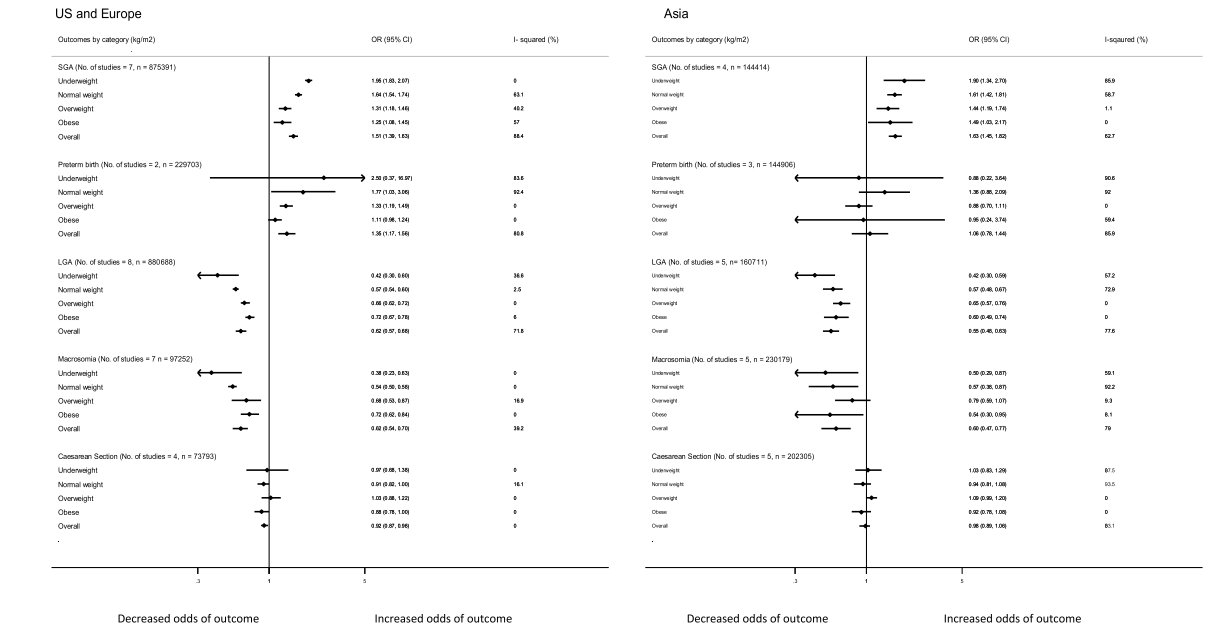

Fig. 2 a Pooled odds ratio for individual outcomes for USA and Europe combined vs Asia, for the association between GWG below guidelines with adverse outcomes. **b** Pooled odds ratio for individual outcomes for USA and Europe combined vs Asia, for the association between GWG above guidelines with adverse outcomes

Table 6 Odds ratios for pregnancy outcomes by regions

Outcome	USA and Europe		Asia overall		Regional BMI studies (Chinese and Korean)		WHO BMI studies (Japanese and Taiwanese)	
	GWG < guidelines	GWG > guidelines	GWG < guidelines	GWG > guidelines	GWG < guidelines	GWG > guidelines	GWG < guidelines	GWG > guidelines
SGA	1.51 (1.39, 1.63)	0.65 (0.62, 0.69)	1.63 (1.45, 1.82)	0.69 (0.63, 0.76)	1.43 (1.2, 1.7)	0.65 (0.57, 0.75)	1.77 (1.56, 2.01)	0.70 (0.63, 0.79)
Preterm birth	1.35 (1.17, 1.56)	0.83 (0.74, 0.94)	1.06 (0.78, 1.44)	0.71 (0.58, 0.87)	N/A	N/A	N/A	N/A
LGA	0.62 (0.57, 0.68)	1.93 (1.81, 2.06)	0.55 (0.48, 0.63)	1.68 (1.51, 1.87)	0.61 (0.48, 0.76)	1.86 (1.66, 2.09)	0.49 (0.39, 0.62)	1.49 (1.18, 1.87)
Macrosomia	0.62 (0.54, 0.70)	1.87 (1.70, 2.06)	0.60 (0.47, 0.77)	2.18 (1.91, 2.49)	0.75 (0.68, 0.83)	2.0 (1.71, 2.34)	0.52 (0.31, 0.88)	2.76 (2.25, 3.38)
Caesarean section	0.92 (0.87, 0.98)	1.26 (1.21, 1.33)	0.98 (0.89, 1.06)	1.37 (1.30, 1.45)	0.94 (0.85, 1.04)	1.43 (1.34, 1.52)	1.02 (0.92, 1.14)	1.32 (1.19, 1.46)

N/A Unable to perform meta-analysis for preterm birth because less than 2 studies within each region

Meta-regression

Substantial heterogeneity (I^2 > 50%) was present for GWG below guidelines for SGA (USA/Europe and Asia), preterm birth (USA/Europe and Asia), LGA (USA/Europe and Asia), macrosomia (Asia) and caesarean section (Asia), and for GWG above guidelines for SGA (USA/Europe), preterm birth (USA/Europe and Asia), LGA (USA/Europe and Asia), macrosomia (USA/Europe and Asia) and caesarean section (Asia).

Where there was sufficient data available, we performed a meta-regression analysis to investigate possible sources of heterogeneity, including percentage of smokers in pregnancy, mean age and percentage nulliparity (Additional file 8) in studies from the USA/Europe and Asia.

The effect of GWG below guidelines on SGA (p < 0.0001) for USA/Europe was associated with mean maternal age (p < 0.0005) and nulliparity (p < 0.0005) and marginally associated with smoking (p = 0.056). The GWG below guidelines effect on LGA (p = 0.002) for USA/Europe was associated with mean maternal age (p = 0.021) and nulliparity (p < 0.005). The effect of GWG above guidelines on LGA was significantly associated with nulliparity (p = 0.025) and marginally associated with mean age (p = 0.084) for the USA/Europe. Heterogeneity was unexplained for the remaining outcomes.

Publication bias

There was no evidence of publication bias for SGA, LGA, macrosomia or caesarean section (Additional file 9). Assessment for publication bias was not assessed for preterm birth (less than five studies).

Risk of bias

Participants were selected from maternity clinics or from large datasets (Additional file 10). Apart from two studies [17, 31], there was adequate description of inclusion and exclusion criteria. Studies were mostly retrospective, with three prospective studies [14, 25, 28] and one unspecified [31]. Given the nature of observational studies, attrition bias was not considered relevant. Performance bias was difficult to assess. Very few studies provided information regarding diet/exercise advice given and whether this differed between groups. The overweight and obese women may have been treated more intensively, and this could be a source of bias. However, we postulate this difference would be similar across studies and therefore propose that studies carry a low risk of performance bias overall.

There were three studies with moderate risk of bias and 16 studies with low risk of bias. Main reasons for moderate risk of bias included self-reported final weight (detection bias), self-reported outcome measures (detection bias), failure to report all outcomes (report bias) and insufficient adjustment for confounding variables (confounding bias). Authors on 15 studies reported no conflict of interest.

Discussion

In this study of 1,309,136 pregnancies, we present a systematic review, meta-analysis and meta-regression incorporating women from diverse ethnicities across three continents, contemporary cohorts and from across the BMI range. We explore ethnic differences in prepregnancy BMI, prevalence of GWG outside IOM guidelines and maternal and neonatal health outcomes between women living in the USA, western Europe and east Asia. Within Asia, we compare studies applying regional and WHO BMI categories. Women in the USA and Europe have higher prepregnancy BMI, higher prevalence of GWG above guidelines and lower rates of GWG below guidelines than women in Asia. However, when applying regional BMI categories, women in Asia have similar

GWG above guidelines to the other continents, but retain lower prevalence of GWG below guidelines. GWG outside guidelines is associated with adverse health outcomes across all regions. A greater percentage of women in Asia had GWG below guidelines, using WHO BMI (60%) compared to regional BMI categories (16%), yet WHO BMI was not accompanied by increased risks of adverse outcomes.

Given that Asian women have greater risks of health complications at a lower BMI, Asian countries often use lower BMI cut-offs for overweight and obese categories. However in 2004, a WHO review of relevant evidence concluded there was no clear cut-off for overweight and obesity for those of Asian ethnicity, and thus WHO did not change their current BMI guidelines [37]. They did, however, identify trigger points of > 23 kg/m^2 and > 27.5 kg/m^2, representing increased and high risks respectively for public health action. In practice, BMI categories commonly used in China [16, 26, 31] are underweight BMI < 18.5 kg/m^2, normal weight 18.5–23.9 kg/m^2, overweight 24–28 kg/m^2 and obese ≥28 kg/m^2. In Korea, the classifications are underweight BMI < 18.5 kg/m^2, normal weight 18.5–22.9 kg/m^2, overweight 23–25 kg/m^2 and obese ≥25 kg/m^2 [12, 34]. Studies from Taiwan [38, 39] and Japan used WHO BMI categories [40] despite Japanese Society of Obesity guidelines that define obesity at a BMI ≥ 25 kg/m^2 [41]. The European Board and College of Obstetrics and Gynaecology (EBCOG) [42] notes difficulties in accurately comparing prevalence of prepregnancy BMI groups internationally with heterogeneity of data sets. However, comparison is important across regions to inform our understanding of relationships between GWG and pregnancy outcomes. To the best of our knowledge, this is the only systematic review comparing prepregnancy BMI and exploring relationships to GWG and health outcomes across international settings. We have compared Asian studies using regional and WHO BMI categories in assessment of prepregnancy BMI, GWG and pregnancy health outcomes to explore applicability of regional and WHO BMI categories in applying IOM GWG guidelines.

Applying WHO prepregnancy BMI categories, the USA had the greatest prevalence of overweight and obesity at 43%, consistent with trends from the 2013–2014 National Health and Nutrition Examination Survey (NHANES), with 37% of reproductive-aged women obese [43]. This is significant as, preconception, a higher BMI independently increases pregnancy complications including GDM, preeclampsia, caesarean section and LGA [44, 45]. In contrast, Asia had the greatest prevalence of women in normal weight and underweight categories. A lower BMI preconception is associated with increased risks including SGA [46]. The high prevalence of prepregnancy BMI outside of the healthful range shown here highlights the critical need to focus on achieving healthy preconception weight, especially in the USA, but also across Europe and Asia.

Women in the USA and Europe had higher GWG above guidelines than women in Asia. However, in studies applying ethnic-specific regional BMI categories, women in Asia had similar rates of GWG above guidelines. The prevalence of GWG above guidelines is consistent with observational studies [47–50]. Excess GWG increases adverse pregnancy outcomes, independent of BMI, as demonstrated here, and also increases postpartum weight retention and obesity [45, 51]. A systematic review of postpartum weight retention in Asian women found that whilst prepregnancy BMI had an impact, GWG was the most important predictor [11], supporting the clinical relevance of our findings on long-term contribution to obesity. Here we have advanced the literature to highlight the high prevalence of GWG above guidelines across the USA, Europe and Asia and show the impact of using regional BMI categories on the application of IOM guidelines.

Exploring health outcomes by GWG, we combined USA and Europe to ensure adequate numbers for meta-analysis and compared USA/Europe to Asia. Across regions, GWG below guidelines was associated with a higher risk of SGA and preterm birth, compared to GWG within guidelines. Likewise across regions, GWG above guidelines was associated with a greater risk for LGA, macrosomia and caesarean section. For women in Asia, adverse outcomes were noted applying both regional and WHO BMI categories. We were generally unable to compare differences in adverse health outcomes because ORs between regions were similar with overlapping CIs. Further research using both regional and WHO BMI categories in all studies of GWG and health outcomes may be useful. We also support the recommendations for standardisation of GWG categories and core outcome parameters to enable more accurate comparisons for future studies [42, 52].

With high prepregnancy BMI, high rates of GWG above guidelines and clear adverse health outcomes shown here across the USA, Europe and Asia, and in our pooled data analysis [5], intervention is clearly vital. The Journal of the American Medical Association editorial accompanying our recent data analysis on GWG discussed barriers to healthful lifestyle intervention during pregnancy in addressing GWG and improving health outcomes [53]. Barriers included inadequate evidence of improvement of adverse pregnancy outcomes and modest changes in GWG. Yet, the largest individual patient data (IPD) analysis of 36 randomised controlled trials in pregnancy (~ 12,000 women) [6], recently published in *The BMJ*, demonstrates that even modest reduction in

excessive GWG improves outcomes, reducing caesarean section, preterm birth and GDM, the latter being particularly modifiable with physical activity intervention. Reported results were independent of maternal characteristics including age, BMI, parity and ethnicity, enhancing generalisability of the findings. It appears that even modest changes to lifestyle and GWG effectively reduce adverse health outcomes, affirming the need for implementation of healthful lifestyle in routine antenatal care for public health impact [54].

There may also be differences to consider within Asia. Comparing Asian studies, prepregnancy BMI was similar. Overall, 16% of Chinese women were underweight, 74% normal weight and 9% overweight and obese. These values are lower than those of recent cohort studies, where 15–28% of reproductive-aged women in China are above healthy weight [13, 47]. This contrasted with Japan, with 18%, 71% and 11% respectively. In China 53% of women gained above GWG guidelines consistent with the USA and Europe. In Japan GWG below guidelines was 64%, with only 7% above. These differences arguably occur because WHO BMI categories were applied in Japan. Differences may also relate to ethnic variation. In Singapore, difference in GWG between ethnicities was postulated to be due to difference in diet quality and psychosocial factors [55]. However we postulate that the degree of observed difference primarily related to application of BMI categories. Asian studies have already suggested the need for specific guidelines [56]. In 2000, Chinese-specific guidelines for GWG [57] were developed, but have not been commonly adopted, with most Asian studies using mainly Caucasian-derived IOM GWG guidelines [55]. A call has been made for multi-centre collaboration to create optimal GWG guidelines for Asian women using modified BMI categories [58]. Here however, we demonstrate that applying regional BMI categories generated GWG patterns and health outcomes similar to those in the USA/Europe. With regional BMI categories, apparent higher risks of macrosomia and caesarean section were demonstrated. Overall our data are reassuring for clinicians and policy makers that IOM GWG guidelines are applicable in women of Asian background, provided regional BMI categories are used, to avoid overestimation of GWG below recommendations that are not accompanied by increased risks of adverse outcomes.

Limitations of our study include the lack of cohorts from developing countries and the exclusion of non-English language articles. It did not include studies from eastern Europe and south Asian countries, which have historical and ethnic differences from adjacent western European and east Asian countries respectively, yet this is the broadest systematic review and meta-analysis performed to date. For the meta-analysis, we combined the USA and Europe into one group, due to inadequate reported outcomes. Within each study there may be heterogeneity regarding race/ethnicity, and results should not be interpreted that the sample represented the country of origin. The European and Asian studies did not provide demographic data, and we have assumed the populations in these studies to be largely homogeneous. Studies from the USA do include some women from Asia, and where reported proportions are small, reporting is inconsistent, limiting capacity to interpret the overall prevalence of Asian women in US and European studies. Preterm birth was not adjusted for gestational age, potentially resulting in less total gestational weight gain than would have been otherwise attained. Meta-analyses for GDM could not be performed due to deficiencies in the primary data sets. Heterogeneity among studies may affect the reliability of the results, although this was only relevant for the effect of GWG below guidelines in SGA and LGA in USA/Europe. Lastly, we included studies published before 2009 IOM guidelines, so treating physicians and midwives may have had different GWG targets and guidelines compared to studies from after that time.

Strengths are the inclusion of common maternal and infant risks associated with GWG below and above the IOM 2009 guidelines across the entire prepregnancy BMI spectrum, with an analysis across three continents. Notably, a quarter of the women in these studies were from Asia. This is the only systematic review that has compared Asian studies applying regional compared to WHO BMI categories. We searched four databases, performed a thorough risk of bias appraisal and sought international collaboration to facilitate reanalysis, enabling broad inclusion of data in excess of 1.3 million pregnant women. The collaboration with authors has enabled data in a more homogeneous format for meta-analysis, with unprecedented data integration and meta-analysis.

Conclusions

In this study of 1,309,136 pregnancies, incorporating women from diverse ethnicities, contemporary cohorts and from across the BMI range, we show that women from the USA and Europe have higher prepregnancy BMI than those from Asia (even when applying regional BMI categories). In the USA and Europe, GWG above guidelines appeared higher than in Asia and GWG below guidelines was highest in Asia. However in Asian studies applying regional BMI categories, GWG above guidelines was similar across the USA, Europe and Asia. In Asia, regional BMI categories may be more applicable than WHO BMI categories when applying IOM GWG guidelines. Across all prepregnancy BMI categories and in different ethnicities, insufficient GWG is associated with increased risk of SGA and preterm birth and excess GWG with increased risk of LGA, macrosomia and

caesarean section. Risks associated with excess GWG may be higher in women from Asia. These findings have practice and policy implications. This work attests to the broad applicability of the 2009 IOM guidelines, when Asian regional BMI categories are applied. As lifestyle interventions in pregnancy increase attainment of recommended GWG and show health benefits, IOM implementation of GWG guidelines and pregnancy lifestyle interventions should be considered broadly across maternity care [59, 60].

Additional files

Additional file 1: Search terms. (DOCX 17 kb)

Additional file 2: Additional methods. (DOCX 14 kb)

Additional file 3: Table S1. Descriptive characteristics of 23 included studies. (DOCX 27 kb)

Additional file 4: Figure S1. Summary of pooled OR for the association between gestational weight gain below and above guidelines for adverse outcomes. (DOCX 220 kb)

Additional file 5: Table S2. Body mass index at onset of pregnancy for Asian studies. (DOCX 17 kb)

Additional file 6: Table S3. Gestational weight gain during pregnancy for Asian studies. (DOCX 14 kb)

Additional file 7: Figure S2. Asian subgroup analysis: studies using local BMI categories (China, Korea) vs WHO BMI categories (Japan, Taiwan). Summary of pooled OR for the association between gestational weight gain below and above guidelines for adverse outcomes. (DOCX 106 kb)

Additional file 8: Table S4. Meta-regression. (DOCX 21 kb)

Additional file 9: Figure S3. Publication bias. (DOCX 53 kb)

Additional file 10: Table S5. Summary of risk of bias assessment. (DOCX 20 kb)

Abbreviations

BMI: Body mass index; GDM: Gestational diabetes mellitus; GWG: Gestational weight gain; IOM: Institute of Medicine; LGA: Large for gestational age; SGA: Small for gestational age; WHO: World Health Organization

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

RFG, SKA, MM, SR, JB and HJT participated in the conception, design and implementation of the study. RFG and SKA extracted data. RFG and HJT wrote the first manuscript. RFG and SR performed the statistical analysis. MHB, NL, GH, FC, HH, YJK, MH, WS, MHK, AB, RD and JHC provided data reanalysis. All authors reviewed and approved the final manuscript.

Ethics approval and consent to participate

This systematic review and meta-analysis includes previously published observational studies. We could not influence the design of the prior studies upon which this work is based and cannot comment on individual ethics approval or consent. Patients were not involved in the conduct of our epidemiological study, and there is no identifiable data.

Competing interests

Author/Professor Boyle reports personal fees from Pfizer, outside the submitted work. The authors declare that they have no competing interests.

Publisher's Note

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2.4 Summary

In the first publication, I explored associations between GWG above and below IOM guidelines in more than 1 million women in epidemiological research. The majority of women had weight gain outside of guidelines. I also demonstrated novel findings in those women with inadequate GWG, showing the risks for maternal and infant outcomes associated with weight gain less than guideline recommendations.

In the second publication, I explored data on the associations between GWG and adverse outcomes stratified by continents and subgroups of countries within continents, where different local criteria were applied. In US and Western Europe, women have higher pre-pregnancy BMI and higher rates of GWG above guidelines than women in East Asia. When using regional BMI categories in East Asia, rates of GWG above guidelines and adverse outcomes are similar across the three continents. This work affirmed the US IOM guidelines for application internationally, including demonstrating applicability in the 60% of the world's population who are of Asian ethnicity.

These publications add considerably to the literature by identifying the prevalence and risks associated with GWG outside recommendations, across continents and ethnicities. In the next chapters of my thesis I will explore healthy lifestyle interventions to optimise GWG and prevent these complications.

Chapter 3. Evaluation of the Healthy Lifestyle in Pregnancy Project (HiPP) to optimise gestational weight gain for women with obesity

3.1 Introduction

In this chapter, I move beyond epidemiology and risks explored in chapter 2 to address interventions to achieve healthy lifestyle and recommended weight gain in pregnancy.

Reproductive-aged women are now targeted as a high-risk group with recommendations to limit GWG and encourage postpartum weight loss according to the World Health Organisation Action Plan (27). Pregnancy offers significant opportunities for obesity prevention due to a combination of factors – women have frequent antenatal visits and contact with healthcare providers and mostly have enhanced motivation towards healthy lifestyles to ensure the health of their child (28, 29).

Monitoring weight alone is ineffective (30, 31), but its efficacy is improved when used in combination with interventions. Success factors are those that focus on diet or combined interventions (8) (rather than exercise alone) and use behavioural strategies, motivational interviewing and technology to assist delivery. Systematic reviews (8) and individual patient data (IPD) meta-analyses (7) of lifestyle interventions in pregnancy prevent excess GWG gain and reduce pregnancy complications including caesarean section. When supplemented with study level data from non-IPD studies, GDM was also reduced (7). A recent systematic review including data over the last 3 years additionally showed GDM reduction as well as hypertensive disorders of pregnancy and NICU admission (32).

However, RCT's have poor participant uptake and penetration, limiting translational and health impact. Despite clear health needs and evidence for efficacy of lifestyle interventions in pregnancy, a major gap persists with inadequate translation of healthy lifestyle change integrated into routine preconception and antenatal care. There is a need for implementation research to fill this gap. Pragmatic implementation trials generate evidence in 'real-world' settings, demonstrate reach, penetration, participation, adherence and cost-effectiveness (33). They are conducted in the context of usual clinical care, allowing comparison of clinically relevant alternatives and produce findings that can be easily and promptly implemented and scaled.

This is the basis for chapter three, where we developed, implemented and evaluated the Healthy Pregnancy Service, for women with a BMI of 35–43 kg/m², at a Monash Health site in Victoria as a pragmatic implementation clinical trial of an effective lifestyle intervention embedded in routine maternity care. We wanted to evaluate the service from a broad perspective, in the first instance, understanding the effects on GWG, maternal and infant outcomes as well as uptake and adherence; whilst also understanding the perspective of the health professionals and the experience of the pregnant women.

This clinical trial was powered for primary outcomes of GWG. Secondary outcomes included implementation (penetration, participation and maintenance). These outcomes are presented in 3.2.

Alongside this, we aimed to capture implementation barriers and enablers, and participant experiences to inform scale-up. Here, we determined that qualitative analysis would be optimal to evaluate secondary outcomes. To prepare for this, I completed a qualitative research methods course, consulted with researchers in MCHRI with expertise in this field and performed a literature review. For evaluation of the health professionals' experiences (presented in 3.3), I used semi-structured interviews. For evaluation of pregnant women's experiences, I used semi-structured interviews and questionnaire data, applying a mixed-methods model (presented in 3.4).

I was able to expand my learnings from the patient experience of GDM in chapter four to establish my evaluation of both the pregnant women's experiences and staff experience, using the questionnaires and learnings from the quantitative study in GDM to inform the construction of questionnaires and semi-structured interviews.

This chapter presents the evaluation of this service in three modes, each forming an individual publication (3.3 has been published and 3.2 and 3.4 are under review).

3.2 A Pragmatic lifestyle intervention implemented into antenatal care to optimise gestational weight gain for women with obesity: The Healthy Lifestyle in Pregnancy Project (HiPP)

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A pragmatic lifestyle intervention implemented into antenatal care to optimise gestational weight gain for women with obesity: The Healthy Lifestyle in Pregnancy Project (HiPP)

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A Pragmatic Lifestyle Intervention Implemented into Antenatal Care to Optimise Lifestyle and Gestational Weight Gain for Women with Obesity: The Healthy Lifestyle in Pregnancy Project (HiPP)

--Manuscript Draft--

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	Helena J Teede
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Abstract:	Background: Excess gestational weight gain (GWG) is associated with adverse maternal and infant outcomes. This trial evaluated effectiveness of lifestyle intervention implemented into routine antenatal care in reducing excess GWG. It also sought to assess intervention uptake and adherence. Methods: This pragmatic-controlled trial was embedded in a large hospital maternity service. Women with a pre-pregnancy body mass index of 35-43kg/m² were recruited prior to 23 weeks gestation. The intervention group attended routine antenatal care with an embedded behavioural lifestyle intervention delivered by a Health coach, supported by a Physician over five sessions. The comparison group received standard antenatal care. This study was registered with ANZCTR (no.12620000985987). Findings: Overall, 277 women were studied (n=157 intervention, n=120 standard care). The intervention did not significantly alter the proportion of women with GWG above Institute of Medicine (IOM) recommendations (32% of intervention and 33% of standard care, p=0·91). There was a reduction in total GWG (-1·4kg [95% CI -2·6,-0·1],p=0·04 adjusted), which remained significant when excluding women who developed gestational diabetes (-2·0kg [95% CI -4·0,-0·2],p=0·03 adjusted). Mean GWG/week was lower in the intervention (0·32kg/wk vs 0·37 kg/wk,p=0·02, adjusted). Intervention uptake was 95%, and 87% attended 4 of 5 sessions. Interpretation: Lifestyle intervention embedded in routine antenatal care for women with obesity lowered total GWG and GWG/week, but did not alter proportion of women gaining above recommended GWG. Intervention uptake and engagement rates were high. This pragmatic study advances effectiveness and implementation knowledge. Further studies are underway analysing settings, populations and cost-effectiveness to drive translation and scale-up.

TITLE

A Pragmatic Lifestyle Intervention Implemented into Antenatal Care to Optimise Lifestyle and Gestational Weight Gain for Women with Obesity: The Healthy Lifestyle in Pregnancy Project (HiPP)

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ABSTRACT

Background: Excess gestational weight gain (GWG) is associated with adverse maternal and infant outcomes. This trial evaluated effectiveness of lifestyle intervention implemented into routine antenatal care in reducing excess GWG. It also sought to assess intervention uptake and adherence.

Methods: This pragmatic-controlled trial was embedded in a large hospital maternity service. Women with a pre-pregnancy body mass index of 35-43kg/m² were recruited prior to 23 weeks gestation. The intervention group attended routine antenatal care with an embedded behavioural lifestyle intervention delivered by a Health coach, supported by a Physician over five sessions. The comparison group received standard antenatal care. This study was registered with ANZCTR (no.12620000985987).

Findings: Overall, 277 women were studied (n=157 intervention, n=120 standard care). The intervention did not significantly alter the proportion of women with GWG above Institute of Medicine (IOM) recommendations (32% of intervention and 33% of standard care, p=0·91). There was a reduction in total GWG (-1·4kg [95% CI -2·6,-0·1],p=0·04 adjusted), which remained significant when excluding women who developed gestational diabetes (-2·0kg [95% CI -4·0,-0·2],p=0·03 adjusted). Mean GWG/week was lower in the intervention (0·32kg/wk vs 0·37 kg/wk,p=0·02, adjusted). Intervention uptake was 95%, and 87% attended 4 of 5 sessions.

Interpretation: Lifestyle intervention embedded in routine antenatal care for women with obesity lowered total GWG and GWG/week, but did not alter proportion of women gaining above recommended GWG. Intervention uptake and engagement rates were high. This pragmatic study advances effectiveness and implementation knowledge. Further studies are underway analysing settings, populations and cost-effectiveness to drive translation and scale-up.

Key words: Gestational weight gain, intervention, pragmatic clinical trial, obesity, maternal and infant outcomes

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RESEARCH IN CONTEXT

Evidence before this study

It is well established that excess gestational weight gain (GWG) is common, escalating and is associated with adverse maternal and neonatal outcomes. Systematic review evidence indicates that lifestyle interventions effectively reduce excess GWG and adverse outcomes in randomised controlled trials (RCTs). RCTs of lifestyle interventions focus on efficacy and do not reflect or address implementation barriers in real-world settings. They are limited by opt-in selective recruitment, poor penetration, high drop-out or low participation rates, and limit impact in routine care. Implementation knowledge is still limited, impeding scale-up and health impact from a public health perspective. The key remaining barrier is to leverage off efficacy data from RCTs, and deliver implementation research including pragmatic clinical trials to generate evidence in real-world settings and support scale up and health impact. Innovative pragmatic trials are rapidly emerging to overcome the valley of death between efficacy RCTs and real world implementation and scale-up.

Pragmatic clinical trials recruit from and embed trials in routine clinical care, allowing co-design and adaptations for different settings and populations. They optimise penetration and participation and use clinically relevant comparators, assessing a broad range of implementation and health outcomes. They are now vital in lifestyle interventions in pregnancy, to take the evidence base from the 117 RCTs for prevention of excess GWG during pregnancy into practice in real-world settings for broad, public health benefit.

Added value of this study

The Healthy Lifestyle in Pregnancy Project (HiPP) implemented an evidence-based lifestyle intervention embedded in routine antenatal care for women with obesity. Compared to standard care, the intervention demonstrated effectiveness in reducing total and weekly rate of GWG, despite a similar proportion of pregnancies with excessive GWG between intervention and standard care groups. Here, in high risk pregnant women with obesity, we have also demonstrated high penetration, high participation, generalisability in a low socio-economic status (SES) and ethnically diverse population and ongoing maintenance, supporting translation of evidence-based lifestyle interventions into routine care. To our knowledge, this is one of the first implementation studies of evidence-based lifestyle interventions into routine antenatal care and is directly informing intervention expansion.

Implications of all the available evidence

The degree of GWG improvement reported here, has been shown to significantly reduce maternal and neonatal outcomes and to be cost-effective, supporting the case for implementation of effective lifestyle interventions into routine antenatal care. This pragmatic study advances implementation knowledge with further studies underway analysing settings, populations and cost-effectiveness to inform translation and scale-up.

BACKGROUND

Obesity in reproductive-aged women is increasingly prevalent. High pre-pregnancy body mass index (BMI) and excessive gestational weight gain (GWG) both independently contribute to adverse maternal and neonatal outcomes (1), and increase risk of future obesity and non-communicable disease in mothers and children (2). The Institute of Medicine (IOM) recommends guidelines for appropriate GWG based on a woman's pre-pregnancy BMI, to prevent adverse perinatal outcomes (3). Many women exceed these, with a systematic review and meta-analysis of over 1·3 million women demonstrating 47% gain above recommendations (4). Women who are overweight, followed by women with obesity, had the highest prevalence of GWG above guidelines (64% and 60% respectively) (5). GWG above recommendations was associated with a lower risk of small for gestational age (SGA) and preterm birth, and a higher risk of large for gestational age (LGA), macrosomia and caesarean section. In Australia, this pattern is similar with nearly half of women entering pregnancy with overweight or obesity and 42% of these estimated to exceed GWG recommendations (6).

Pregnancy is an ideal time to intervene given women have increased health provider contact and are more motivated to optimise their health to ensure positive outcomes for themselves and their child. A recent systematic review and meta-analysis was completed across 117 randomised controlled trials (RCTs) involving 34,546 women on diet and/or exercise-based lifestyle interventions in pregnancy (7). GWG was significantly lower (-1·15 kg ; 95% CI -1·40 to -0·91) in intervention groups compared to control. Interventions reduced gestational diabetes (GDM) (OR 0·79; 0·70 to 0·89) and total adverse maternal outcomes (OR 0·89; 0·84 to 0·94). There is now unequivocal evidence that lifestyle interventions are effective, and they have also been demonstrated as cost-effective (8).

The key remaining barrier is research and evidence to inform implementation. Intervention is effective, but little has been done to translate evidence into implementation research (7). RCTs of lifestyle interventions focus on efficacy and generally have poor penetration, high drop-out or low participation rates (6, 9) and generate little implementation knowledge, limiting translation, scale-up and health impact (10). Few studies have implemented lifestyle interventions into routine pregnancy care (11, 12). Studies are needed to show whether valuable, cost-effective interventions in 'real-world' settings demonstrate reach, penetration, participation, adherence and maintenance (13). Implementation research includes pragmatic clinical trials generating evidence-based research in 'real-world' settings. They recruit from, and embed trials in routine clinical care, allowing co-design and adaptations for different settings and populations, using clinically relevant comparators, assessing a broad range of clinically-relevant health outcomes (14).

This Healthy Lifestyle in Pregnancy Project (HiPP) is a 'real-world' implementation-efficacy lifestyle intervention trial. Adapting an effective patient-centred diet, exercise and behaviour-change lifestyle intervention and embedding it into routine antenatal care, we aimed to reduce excessive GWG and assess uptake and implementation of the program.

METHODS

Study design

HiPP is a prospective, multidisciplinary, single-site study aiming to reduce GWG in women with obesity. It is embedded within an existing maternity service at a Monash Health hospital, Victoria, Australia, in hospital-based ambulatory maternity care. Australia offers universal freely accessible healthcare and Monash Health is the largest health service nationally, situated in a low socio-economic status (SES), diverse ethnic background catchment . The study was approved by Monash Health and Monash University ethics committees and registered with the Australian New Zealand Clinical Trials Registry (no.12620000985987). Reporting is aligned with the CONSORT extension for pragmatic trials (15).

Participants

Women with a pre-pregnancy BMI of 35-43 kg/m² were eligible for attendance at the service where the lifestyle intervention was embedded. This service provides care for women with a BMI ≥35kg/m² and delivers collaborative care with obstetricians and midwives. Women were allocated to attend this service and received the intervention as part of routine care. Consistent with pragmatic trial design, inclusion and exclusion criteria in the trial were minimal. Women were eligible if they were aged over 18 years, with a singleton pregnancy and no chronic medical conditions requiring specialised care, and their first midwife appointment was before the end of 23 weeks gestation. This time was selected to reflect 'real-world' setting, where many women have their 1st appointment in the second trimester, but also to provide women with sufficient opportunity to attend the majority of their intervention sessions.

The Healthy Pregnancy Clinic was established one year before study data collection. It operates weekly; all eligible women were identified by administration clerks and allocated according to clinic capacity. If clinic capacity was exceeded or the clinic day was inconvenient, women were allocated to standard care in other clinics. Thus, the allocation to the intervention group was made at a clinical service level, based on service capacity limitations and women's convenience factors. Women could opt out of the dedicated Healthy Pregnancy clinic if desired. Women were not required to provide written consent as this was considered a low-risk service evaluation of implemented evidence-based practice in existing maternity services and endpoint were based on routine clinical data. Data was analysed in the intervention if they attended one or more lifestyle sessions.

Standard pregnancy care

Standard pregnancy care included provision of written information regarding healthy eating and recommended recording weight at all visits. Weighing practices were inconsistent, but women identified with inadequate/excessive weight gain were reminded by midwifery and obstetric staff of the need for healthy eating and exercise to assist in weight management.

Embedded lifestyle Intervention Program

The Healthy Pregnancy Clinic includes an integrated evidence-based program, based on the Healthy Lifestyle in Pregnancy intervention (HeLPher) (16). This intervention demonstrated effectiveness in thousands of reproductive-aged women across a range of settings and life-stages, including those at increased risk of GDM (11, 17-19). Here it was adapted with input from multidisciplinary staff and pregnant women, to suit the higher BMI target group, designed as a pragmatic intervention (20). The

intervention is underpinned by social cognitive theory and focuses on simple dietary and physical activity information, supporting behaviour change and self-management of weight, healthy diet and exercise, with skills practised in goal setting , problem solving and relapse prevention. The intervention content was based on prior implementation research and on evidence-based guidelines: IOM guidelines for GWG (3), Australian dietary guidelines for pregnancy (21) and Australian physical activity guidelines (22). All five lifestyle sessions follow a similar structure developing skills practised, and realistic, achievable goals for lifestyle change. Barriers and supports are identified and self-efficacy discussed and assessed. Weight is recorded at each clinic visit.

The intervention team consisted of one health coach, supported by one physician (endocrinologist) functioning within the maternity clinic (consisting of a team of midwives and two dedicated obstetricians). The health coach was dedicated to lifestyle intervention delivery, whilst the physician both delivered and supported the intervention, and provided care for the high proportion of women with GDM and other medical conditions. At the first midwife appointment, the midwife briefly mentioned the five integrated intervention lifestyle sessions that were included in the booking schedule cards. Maternity staff did not directly deliver the intervention but were knowledgeable of the content and reinforced its importance. The first intervention assessment (involving assessment by both health coach and physician) coincided with the first obstetric appointment, typically scheduled between 12-18 weeks. Session 2 occurred between 20-22 weeks, session 3 ~28 weeks, session 4 ~32 weeks and session 5 ~36 weeks. Sessions were booked on the same day as maternity appointments, with flexibility of appointment dates to suit participants. Women were seen by either the health coach or the physician in sessions 2-4 (at the clinicians' discretion, influenced by other comorbidities such as the development of GDM), and by the health coach in session 5, focussing on post-partum lifestyle advice.

In addition to effectiveness, implementation outcomes guided by the RE-AIM framework (addressing the Reach, Effectiveness, Adoption, Implementation, and Maintenance) were captured, aligned with our prior lifestyle work in non-pregnant women (23). Reach or penetration/uptake and participation/adherence was captured. Adoption into the service alongside implementation fidelity, health professional (24) and women's experiences (25) were evaluated, and is presented elsewhere.

Data collection

End-point data was extracted from routinely collected clinical data, from the BOS (electronic birthing outcomes system database) and SMR (scanned medical records). Demographic characteristics were extracted from BOS. Postcodes were used to measure SES based on the Index of Relative Socio-economic Disadvantage (IRSD)(26).This is a socio-economic index summarising a range of information about the socio-economic conditions within an area. IRSD decile score was stratified into deciles ≤3 (very disadvantaged), 4-6 (moderately disadvantaged) ≥7 (less disadvantaged).

Outcomes

The primary outcome of the study, which it was powered for, was the proportion of participants who developed excessive GWG according to IOM recommendations, aiming to detect a 20% difference in the proportion that exceeded IOM guidelines between the groups. An additional primary outcome (not powered for) was GWG, calculated as the maternal weight closest to the 36-week visit (+/- 3 weeks) minus the weight measured at first antenatal visit, and GWG per week measured as total GWG divided by the number of weeks.

Pre-pregnancy BMI calculation was based on the first antenatal weight. Weight was routinely measured in the maternity clinic using Wedderburn digital personal scales (model TIHD351, China), measuring up to 200kg. Women with preterm birth were not excluded because final gestational weight was measured at 36 weeks and mean preterm birth was 36 weeks.

Secondary outcomes: The study was not powered for maternal and neonatal outcomes however data collected included maternal outcomes; incidence of GDM, insulin use, oral glucose tolerance tests (OGTT), induction of labour (IOL), caesarean delivery, hypertensive disorders of pregnancy (pregnancy-induced hypertension, pre-eclampsia and eclampsia) and preterm birth (before 37 weeks). Neonatal outcomes included birthweight, SGA (gender-specific birth weight below the 10th percentile), LGA (gender-specific birth weight above the 90th percentile), calculated from the Australian national birthweight percentiles (27).

GDM was diagnosed by 2-hour 75 g OGTT, performed early in the 2nd trimester if high risk, and/or at 24-28 weeks gestation. Negative early screenings were repeated at 24-28 weeks. GDM was diagnosed using the International Association of the Diabetes and Pregnancy Study Groups (IADPSG) guidelines . Women with GDM underwent a group education session by diabetes nurse educators, covering blood glucose monitoring and diet, plus a review by an endocrinologist. Women in standard care were referred to the GDM clinic for ongoing care; women in the intervention were treated by the physician in the Healthy Pregnancy Clinic during their usual appointments.

Power calculation and participant recruitment

The study was designed to have 80% power to detect between-group difference of 20% in the primary outcome, with a 0·05 two-tailed alpha level. Calculations were based on the proportion of women exceeding IOM recommendations (4), on a meta-analysis of interventions reporting 20% reduction in excess GWG (28), and on the rate of eligible women attending the maternity clinic in the previous year, with an estimated ratio of 2:1 in the intervention: standard care. This corresponded to 240 women, 160 in the intervention, 80 in standard care. Given the 'opt-out' study design and that prior HeLPher studies had under 10% withdrawal, we did not expect a significant drop-out rate and did not adjust for this. Participant recruitment occurred between maternity visits after 1 July 2016 and ended with women who birthed on/before 31 December 2018. During data collection, clinic capacity and ratio of intervention to standard care changed slightly within the maternity services. Data collection is continuing for additional endpoints including maternal and neonatal outcomes.

Statistical analysis

Primary analysis: multinominal logistic regression to compare primary outcomes between intervention and standard care. Secondary analysis: Linear regression models to examine GWG and GWG/week and compare intervention and standard care. Other analysis: Linear and logistic regression to examine other outcomes and compare groups.

All regression models were built following this procedure: First, we conducted multiple univariate regressions with these independent variables: BMI, maternal age, parity group (0, 1 or ≥2), smoking status (yes/no), country of birth (Australia/overseas), IRSD (≤3, 4-6 or ≥7) and GDM. Independent variables producing p-values ≤0·2 in the univariate regression were considered for inclusion into the final multivariate analysis. Correlation between variables considered for inclusion into the multivariate

model were assessed but not present. Therefore, final multivariate models included all the independent variables identified by the univariate analyses.

Subgroup analysis was performed: (a) excluding women who developed GDM; they received additional lifestyle intervention during routine GDM care, potentially contaminating the evaluation of intervention impact; (b) combining the intervention group with those that developed GDM in standard care (as these women also received lifestyle intervention); (c) intensity of interventions was compared using Anova and t-tests.

Where appropriate, Cohen's effect size was used for continuous outcomes. Odds ratios and mean differences were reported with 95% confidence intervals. To examine the robustness of the results, bootstrap analysis was performed. All analyses were performed using STATA software, version 15·0.

Role of the funding source

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

RESULTS

The flow of participants is presented in Figure 1.

Between 1 July 2016 and 31 December 2018, 339 were assessed for eligibility and 277 were included in the study, 157 in lifestyle intervention and 120 in standard care.

The baseline characteristics are described in Table 1. Women in the intervention had a higher BMI (38·6 kg/m² vs 37·6 kg/m²), were younger (29·9 vs. 31·4), and more likely to be nulliparous (42% vs 24%); all p<0·005. Smoking rates were comparable between groups. A higher proportion of women in the intervention were Australian born (68% vs 53%). Overseas-born women were most likely to be from South Asia (11% intervention; 17% standard care) or New Zealand (8% intervention; 9% standard care). Women in the intervention had higher IRSD decile (28% ≤3 vs 46% ≤3) and earlier gestational age at first visit (13·8 weeks vs 14·7 weeks). Gestational age at 36-weeks was comparable between groups (mean 35·9) as were maternal PCOS status, past history of GDM and family history of diabetes.

Gestational weight gain

Table 2 shows the proportion of women outside IOM guidelines, total GWG and total GWG/week. IOM recommendations were exceeded similarly, by 32% in the intervention and 33% in standard care. Univariate regression demonstrated a relationship between parity and GWG: parity ≥2 had a higher association with GWG below guidelines and a lower association with GWG above guidelines, independent of treatment group (appendix, text 1). In the multivariate analysis, there was no difference between groups.

Women with GWG below guidelines showed no significant difference in weight gain between groups (appendix, text 2). For those with GWG above guidelines, the intervention group had 2·2kg less weight gain than standard care (p=0·02).

The mean total GWG was 7·14kg in intervention, and 7·76kg in standard care. Multivariate analysis (adjusted for BMI, maternal age, parity group and IRSD decile) showed a near-significant difference between the groups (β coefficient -1·4; 95% CI -2·8, 0·1, p=0·06), which was significant after bootstrap analysis (-1·4 (-2·6, -0·1), p=0·04). GWG/week was also lower in the intervention (0·32kg vs 0·37kg) on multivariate analysis (-0·10 (-0·1, 0·0) p=0·02)).

Subgroup analysis, excluding women who developed GDM (and received additional lifestyle intervention) from both groups, showed less weight gain in the intervention group on multivariate analysis for total GWG (-2·0 (-4·0, -0·2),p=0·03) and GWG per week (-0·1 (-0·2, 0·0),p<0·05). Subgroup analysis combining all women in the intervention group with women in standard care who developed GDM and therefore had lifestyle intervention, also showed a difference between groups (-2·36 (-3·80, 0·93),p=0·001) (appendix, table 1).

The intensity of lifestyle intervention was analysed (appendix, table 2), comparing women who did and did not develop GDM in both intervention and standard care groups. There was a difference in weight gain across the four groups (p=0·01), with standard care without GDM used as the comparator. Standard care women with GDM had the lowest weight gain (5·3kg), followed by intervention women with GDM (6·9 kg), then intervention without GDM (7·3 kg), and standard care without GDM (8·8kg).

Maternal and neonatal outcomes

Table 3 shows maternal and neonatal outcomes. There was no difference in GDM between intervention (34%) and standard care (30%). The proportion requiring insulin was similar (17 vs 14%). There was a lower fasting glucose on OGTT with intervention (5·07 mmol/L vs 5·38 mmol/L, p=0·01, unadjusted), however the result was non-significant on multivariate analysis.

The intervention group had lower caesarean delivery (38% vs 51%, unadjusted OR 0·60 (0·37, 0·97), p=0·04). However, the proportion with previous caesarean delivery in standard care was significantly higher (45% vs 13%, p<0·05) (appendix, table 3). After adjusting for maternal age, smoking, previous caesarean section and GDM, this difference was non-significant. Induction of labour was higher in the intervention group (OR 2·06 (1·27, 3·35), p=0·004) but non-significant on multivariate analysis.

There was no difference in other maternal or neonatal outcomes. There were 10 preterm births, with mean gestation 36·2 weeks.

Process evaluation of intervention

Participants allocated to intervention were analysed in the intervention if they attended ≥1 session. Ten participants allocated to intervention did not attend any lifestyle sessions and were analysed in standard care (two of these had insufficient GWG measured so were subsequently excluded), corresponding to an intervention uptake of 95% (157 out of 165). Hence the reach/penetration of the intervention was high in this population.

Overall, 6% of women attended one-two sessions; 6% attended three; 34% attended four; 53% attended the full five sessions or more. Some attended additional sessions if they developed GDM, where lifestyle coaching was combined with GDM management. Overall 87% attended four sessions or more (appendix, Table 4). There was no correlation between the number of visits and total GWG. Further process and implementation evaluation is underway. Data collected but not presented here

includes a substudy with women completing questionnaires at first and final visits to assess behaviour change and satisfaction; interviews with women (25) and staff (24) to understand barriers and enablers of behaviour change; and review of health records to assess program fidelity. The Healthy Pregnancy Clinic with embedded lifestyle intervention has been maintained within the clinical setting with plans to scale this more broadly.

Discussion

Gestational weight gain commonly exceeds recommendations causing adverse maternal and neonatal outcomes. RCTs of lifestyle interventions reduce GWG, improve outcomes and demonstrate cost-effectiveness (8). However, key barriers remain in implementation of evidence into practice (29), with limited research to inform guidelines and translation. In this implementation effectiveness trial, embedding an evidence-based lifestyle intervention into routine antenatal care for women with obesity lowered total GWG and weekly GWG, although the proportion of pregnancies with excessive GWG was similar in both groups. Additional lifestyle intervention was delivered to women diagnosed with GDM in both intervention and standard care groups. Therefore, women in the standard care group without GDM were the only group not receiving lifestyle intervention, and this group recorded the highest GWG. Within the Healthy Pregnancy Clinic, alongside efficacy, intervention reach, penetration and participation rates were high, and the service has been maintained.

Like other lifestyle intervention studies (30, 31), we found no difference in the proportion of women exceeding GWG guidelines. However, for women who did exceed GWG guidelines, the intervention group had 2·2kg less GWG than those in standard care. For women who had GWG below guidelines, there was no difference in the GWG between groups, a reassuring finding given the concern regarding adverse effects associated with inadequate GWG, even in women with obesity (32). In recent large evidence-synthesis studies, total GWG is increasingly the primary endpoint (33), and is directly associated with maternal and neonatal adverse outcomes (7). Here, we have demonstrated significant reduction in total adjusted GWG and GWG/week with intervention compared to standard care (mean difference -1·4kg). This is greater than the mean GWG difference of -1·15kg on systematic review of RCTs of lifestyle interventions in pregnancy and demonstrates effectiveness (7).

In many countries including Australia, pregnant women with obesity are not routinely offered lifestyle intervention, despite a high risk of excess GWG and adverse preventable outcomes. Only women who develop GDM in pregnancy routinely receive lifestyle intervention, known to limit GWG (34). This glucocentric approach to offering antenatal lifestyle intervention is increasingly criticised, with calls for personalised risk-based approaches, particularly for those at higher risk, including women with obesity (35). In the subgroup analysis, women without GDM had a significant 2·0kg lower total GWG and lower GWG/week in favour of intervention, highlighting the benefit of lifestyle intervention, independent of GDM. Studies demonstrate that women with obesity and GDM are less likely to exceed IOM guidelines if diagnosed early in pregnancy with longer lifestyle intervention (early GDM 35% vs usual GDM 59%) (36). Furthermore, lean women who develop GDM have limited adverse outcomes. Importantly, offering early lifestyle intervention to women with obesity reduces GDM by ~25%, also improving other adverse health outcomes (7). This supports the move away from “one-size-fits-all” glucocentric approach towards personalised medicine, using internationally validated risk-prediction tools (37), making a strong argument for offering lifestyle intervention in routine antenatal care.

This pragmatic study has a number of strengths; it facilitated an embedded intervention within a maternity service, with intervention appointments scheduled alongside maternity appointments. Our

population was not selective and included women with low SES status, ethnic diversity and non-English language, increasing generalisability of the findings. In contrast to RCTs, where interventions are not maintained after study completion, this intervention has been maintained with plans to scale-up. In contrast to poor adherence or participation in lifestyle intervention RCTs (6, 9), this evaluation demonstrates that intervention penetration was very high, with 95% of women attending at least one session. Participation was high with 87% attending four or more sessions. Given high adherence overall, we were unable to demonstrate an association between session number and total GWG. An additional benefit is the integration of the physician within the team, who provided treatment for women who developed GDM or other medical conditions, streamlining care and enhancing convenience. Further process evaluation of this lifestyle intervention study is underway. This implementation research contributes new knowledge, linking what we know to be effective in highly-selected RCT populations, with what can be achieved in routine clinical care (14).

There were limitations in the study. There were differences in the baseline characteristics between groups, with application of multivariable analysis to adjust for this. Due to pragmatic design women were not randomly allocated to intervention or standard care. Baseline weight measured at the first maternity appointment rather than pre-pregnancy, reduces accuracy of total GWG. This problem is internationally ubiquitous, however the practice applied here has been determined as a satisfactory proxy (38). Furthermore, we cannot demonstrate that women and staff in standard care were not aware of the lifestyle intervention, which raises the potential for selection bias and contamination, yet this would have served only to underestimate intervention effects. The inclusion of a physician into the model to support the intervention may increase costs. Of note, all other effective RCTs with this intervention have not integrated a physician into the service and were similarly effective (11, 17-19).

Conclusions

Lifestyle intervention embedded in routine antenatal care for women with obesity lowered total and weekly GWG, despite a similar proportion of pregnancies with excessive GWG between groups. This degree of GWG improvement has been shown to significantly reduce maternal and neonatal outcomes and to be cost-effective, whilst also demonstrating high penetration, high participation, generalisability and ongoing maintenance, supporting the case for implementation into routine antenatal care. Specific analysis of the most effective delivery modes, dose, staff and setting are underway and remain the key step in translation of evidence into practice, to substantively improve maternal and neonatal outcomes, and contribute to longer-term obesity prevention.

Contributors

RFG had full access to the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. RFG, JAB, AEJ, ALF, CLH and HJT contributed to the study concept and design. RFG, SDC contributed to data acquisition. SDC has verified the underlying data. RFG JAB SDC CLH HJT contributed to analysis and interpretation of data. RFG drafted the manuscript. All authors contributed to the critical revision of the manuscript for important intellectual content and approved the final version. JAB, CLH and HJT supervised the study.

Declarations of interests

We declare no competing interests

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Data sharing agreement

Requests for de-identified data may be requested by written application to the corresponding author and will be considered on an individual basis.

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Figure 1

Figure 1. Flow Diagram of participant selection process

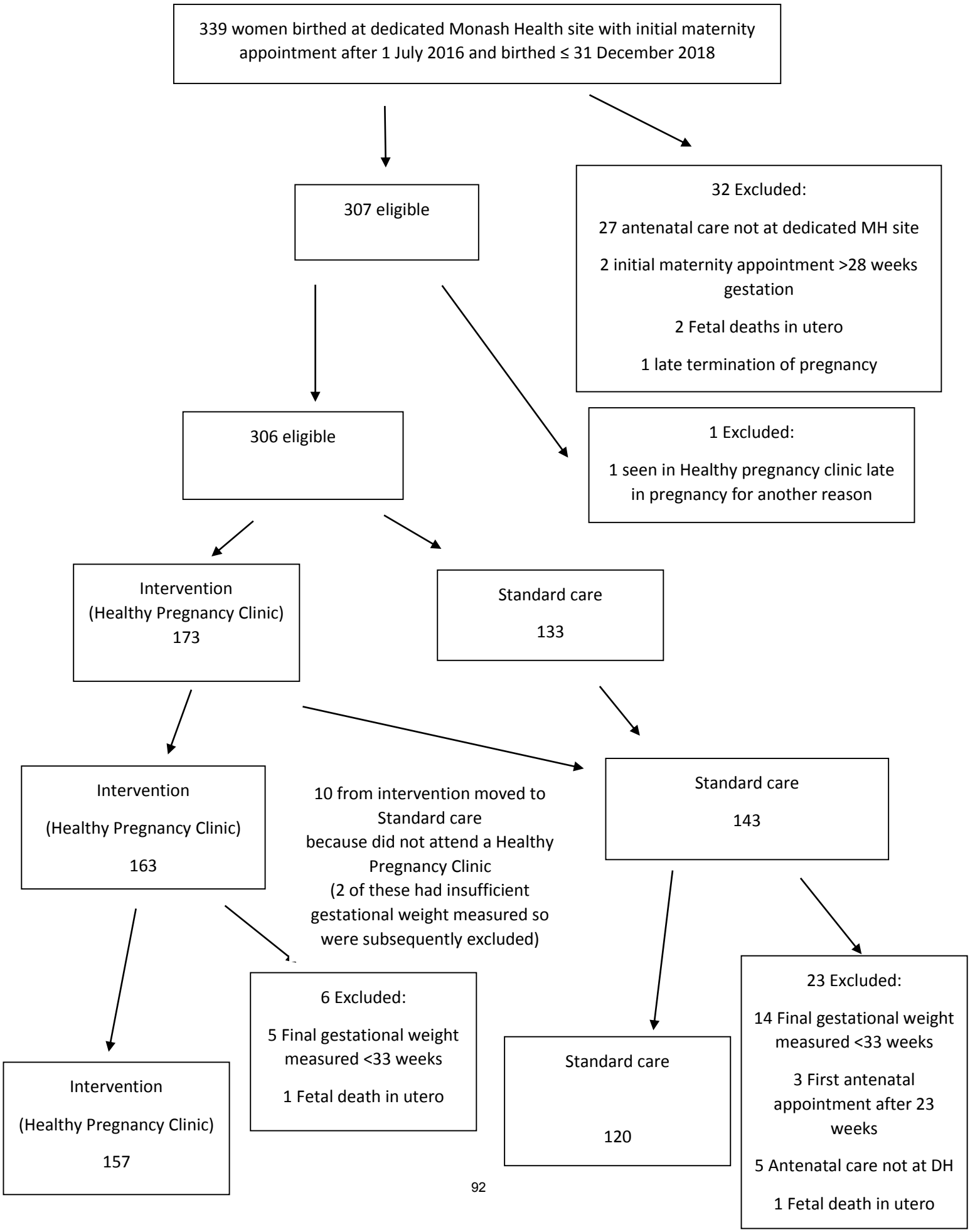

Table 1. Baseline characteristics

	Intervention (N=157)	Control (n=120)	Combined mean	Difference p-value
BMI (kg/m²)	38·6 (2·1)	37·6 (2·1)	38·2 (2·2)	<0·005
Maternal age	29·9 (5·3)	31·4 (4·8)	30·6 (5·2)	<0·005
Parity group 0 1 ≥2	 66 (42) 48 (31) 43 (27)	 24 (20) 46 (38) 50 (42)		 <0·005
Smoking Y N	 33 (21) 124(79)	 16 (13) 104 (87)		0·10
Country of birth Aus/overseas	 Aus 106(68) OS 51 (33)	 63 (53) 57 (48)		0·01
Index of SE disadvantage (decile:) ≤3 4,5,6 ≥7	 44 (28) 83 (53) 30 (19)	 55 (46) 43 (36) 22 (18)		 0·006
Gestation at 1st maternity appointment	13·8(2·5) Range 8·4-22·2	14·7(2·6) Range 10·3-22·6	14·2(2·6)	<0·005
Gestation at 36 week appointment	36·0 (1·0) Range 33-39	36·0 (1·5) Range 33·1-39·4	35·9(1·3)	0·77 33-36 n=85 >36 n=192
Past history of GDM*	16 (12)	14 (13)		0·94
Maternal PCOS	12 (8)	5 (4)		0·23
Family history of diabetes**	77 (51)	73 (62)		0·09

Data presented as N(%), mean (SD) or median (interquartile range)
*data available for 239/277 participants
**data available for 268/277 participants

Table 2. GWG outcomes

Outcome	Intervention	Standard care	Intervention effect				
			p-value	Mean difference (95% CI)	P-value	Adjusted Mean difference (95% CI)	P-value
GWG acc IOM							
				Below vs within:			
Below	55 (35)	39 (32)	0·91	0·9 (0·5, 1·6)	0·72	1.0 (0·6, 1·9)**	0·91
Within	52 (33)	41 (34)		Above vs within:			
Above	50 (32)	40 (33)		0·9 (0·5, 1·6)	0·69	0·6 (0·3, 1·1)**	0·15
				Below vs within:			
Subgroup	40 (38)	30 (36)	0·58	1·1 (0·5, 2·2)	0·18	1·3 (0·6, 2·9)**	0·49
GWG acc. IOM	30 (29)	21 (25)		Above vs within:			
(excl. GDM)	33 (32)	33 (39)		0·8 (0·4,1·5)	0·40	0·5 (0·2, 1·1)**	0·10
Total GWG	7·14kg	7·76kg	0·37	-0·6 (-2·0,0·7)	0·40	-1·4 (-2·8,0·1)#	0·06
						BS -1·4 (-2·6,-0·1)#	0·04
Subgroup total GWG (excl. GDM)	7·28kg	8·81kg	0·08	-1·5 (-3·2, 0·2)	0·07	-2·0 (-4·0, -0·2)#	0·03
				BS -1·5(-3·2, 0·1)	0·06		
GWG per week 36-MAC wt/gest	0·32 kg	0·37 kg	0·19	-0·04 (-0·1, 0·0)	0·19	-0·1 (-0·1,0·0)#	0·02
Subgroup (excl GDM)	0·33 kg	0·41 kg	0·03	-0·1 (-0·2,0·0)	0·03	-0·1 (-0·2, 0·0)#	<0·05

** Model adjusted for parity group, IRSD decile
# Model adjusted for BMI, maternal age, parity group, IRSD decile group
BS = bootstrap

Table 3: Maternal and neonatal outcomes

Outcome	Intervention N=157 no.(%)	Standard Care N=120 no.(%)	Intervention effect			
			OR (95% CI) or Mean difference (95%CI)	p-value	Adjusted OR (95% CI) or Mean difference (95% CI)	p-value
Gestational diabetes	54 (34)	36 (30)	1·22 (0·73, 2·04)	0·43	1·67 (0·95, 2·91) BS 1·67 (0·87, 3·20)	0·07 0·13
GDM requiring insulin	27 (17)	17 (14)	1·26 (0·65, 2·43)	0·50	1·87 (0·90, 3·86) BS 1·86 (0·83, 4·20)	0·09 0·13
OGTT: fasting# (mmol/L)	5·07 (0·46)	5·38(0·63)	-0·31 (-0·54, -0·08)	0·01	-0·18 (-0·42, 0·05)	0·12
OGTT: 1 hr# (mmol/L)	9·34 (1·80)	9·73(2·11)	-0·39 (-1·22,0·44)	0·36	-0·12 (-0·93,0·68)	0·76
OGTT: 2 hr# (mmol/L)	7·49 (1·54)	7·83(1·83)	-0·33 (-1·05, 0·38)	0·36	-0·33 (-1·03, 0·37)	0·35
Caesarean delivery	60 (38)	61 (51)	0·60 (0·37, 0·97)	0·04	1·59 (0·77, 3·24)	0·21
IOL	84 (54)	43 (36)	2·06 (1·27, 3·35)	0·004	1·54 (0·90, 2·63)	0·11
Birthweight (g)	3553 (487)	3581 (485)	-27·57 (-143·66, 88·51)	0·64	-40·75 (-164·01, 82·58)	0·52
LGA >10th %ile	28 (18)	24 (20)	0·87 (0·47, 1·59)	0·65	0·87 (0·45, 1·67)	0·67
Hypertensive disorder pregnancy	18 (11)	17 (14)	0·78 (0·39, 1·60)	0·50	0·65 (0·31, 1·38)	0·27
SGA <10th %ile	4 (3)	4(3)	0·76 (0·19, 3·11)	0·70	N/A	
Preterm delivery <37 weeks	6 (4)	4 (3)	1·15 (0·32,4·18)	0·83	N/A	
Gestation at birth (wks)	39·40	39·37	0·03 (-0·28, 0·35)	0·83	0·02 (-0·29, 0·33)	0·91

Data presented as N(%), mean (SD) or median (interquartile range)
BS = bootstrap

```
# only for those with gestational diabetes

Model adjusted for
GDM- maternal age, parity group, smoking, Aus/OS born
GDM on insulin- maternal age, parity group, smoking, Aus/OS born
OGTT fasting- BMI, maternal age, parity group, smoking
OGTT 1 hour- maternal age, Aus/OS born, IRSD decile group
OGTT 2 hour- maternal age, parity group
Caesarean delivery- maternal age, smoking and previous caesarean delivery, GDM
IOL- BMI, parity group, smoking, Aus/OS born, GDM
Birthweight- BMI, parity group, IRSD decile group, GDM
LGA- parity group, IRSD decile group, GDM
HDP- parity group, GDM
SGA- N/A <10 events so model unadjusted only
PTB- N/A <10 events so model unadjusted only
Gestation- maternal age, smoking, GDM
```

SUPPLEMENTARY MATERIAL

Additional file 1, Text 1

Outcome: GWG according to IOM
Univariate regression model with parity group:
For GWG less than guidelines, for those in parity group (≥2), OR (OR 2·27 (95% CI 1·05, 4·94),p=0·04 and for GWG above guidelines OR 0·37 (95% CI 0·17,0·80) p=0·01.

Additional file 1, Text 2

Outcome: GWG according to IOM
For those with GWG below guidelines, there was no difference in the amount of weight change for the groups (mean difference 0·37 (95% CI -0·16, 0·90; p=0·17).
For those with GWG exceeding guidelines, the intervention group had 2·2kg less GWG than standard group (p=0·02).
Mean difference -2·2 (95% CI -4·09, -0·34).

Additional file, Table 1

Any intervention effect

Outcome	Any Intervention (All intervention and those with GDM in standard care)	Standard care, no GDM	Intervention effect			
			Mean difference (95% CI)	P-value	Adjusted Mean difference (95% CI)	P-value
Total GWG Subgroup total GWG any intervention	6·79kg	8·80kg	-2·02(-3·46,-0·58)	0·006	-2·36 (-3·80, -0·93)	0·001

Additional file 1, Table 2

Rank intensity of intervention (Anova, ttest)

Intervention	Mean kg (SD)	Anova p-value	n	t-test* p-value
Standard care and no GDM	8·8 (6·6)		84	
Intervention and no GDM	7·3 (5·1)		103	0·07
Standard care and GDM	5·3 (4·5)		36	0·004
Intervention and GDM	6·9 (5·3)		54	0·07
Between group		0·01		

*standard care and no GDM as comparator

Additional file 1, Table 3

Relationship between current caesarean delivery and previous caesarean delivery

Delivery mode	Intervention N=157 no.(%)	Standard care N=120 no.(%)	Total
Current caesarean	60 (38)	61 (51)	121
Previous caesarean	17 (13)	50 (45)	67 *
Previous caesarean and current caesarean	15 (88)	45 (90)	60 **
Previous caesarean and current normal vaginal delivery	2 (12)	5 (10)	7**

*only 238/277 responded; intervention 17/128 (13%), standard care 50/110 (45%)

** denominator is no. of previous caesarean

Additional file 1, Table 4

Attendance at Healthy Pregnancy Clinic

No. of visits attended in intervention	No. (%)
1 or 2	10 (6)
3	10 (6)
4	53 (34)
5	71 (45)
≥6	13 (8)

Proportions do not total 100% due to rounding

3.3 The Healthy Pregnancy Service to optimise excess gestational weight gain for women with obesity: A qualitative study of health professionals' perspectives

Rebecca F Goldstein, Ruth Walker, Helena J Teede, Cheryce L Harrison, Jacqueline A Boyle

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The Healthy Pregnancy Service to Optimise Excess Gestational Weight Gain for Women with Obesity: A Qualitative Study of Health Professionals' Perspectives

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Abstract: Maternal obesity is associated with health risks for women and their babies, exacerbated by excess gestational weight gain. We describe health professionals' perspectives in the provision of a Healthy Pregnancy service designed to optimise healthy lifestyle and support recommended gestational weight gain for women with obesity. Semi-structured interviews were conducted with health professionals. Questions were based on the Theoretical Domains Framework (TDF) and deductive thematic analysis was performed. A total of 14 multidisciplinary staff were interviewed. Six themes were identified: 1. health professionals view themselves as part of a team; 2. health professionals reported having necessary skills; 3. experience generated confidence in discussing gestational weight gain; 4. gestational weight gain is considered of variable importance; 5. health professionals want women to be comfortable; 6. the environmental context and resources presented some barriers. Staff were supportive of the Healthy Pregnancy service and valued developing teamwork with staff and rapport with women. Most felt relatively comfortable discussing weight gain with women. Barriers included ability to navigate sensitive topics with women, limited awareness of the intervention among new staff, communication between teams, and waiting time for women. Barriers and enablers to the delivery of an integrated model of maternity care were identified. These findings should inform and improve implementation of service models integrating healthy lifestyle in the antenatal care of women with obesity.

Keywords: gestational weight gain; obesity; midwives; obstetricians; health coach; intervention; implementation; qualitative; health professionals

1. Introduction

High pre-pregnancy body mass index (BMI) and excessive gestational weight gain (GWG) both independently contribute to adverse maternal and neonatal outcomes [1,2], as well as to increased risk of postpartum obesity in mothers and their children [3,4]. The National Academy of Medicine (previously Institute of Medicine, IOM) recommendations for healthy GWG are specific to a woman's pre-pregnancy BMI [5]. A systematic review and meta-analysis [6] of more than one million women revealed that almost half gained above GWG recommendations, leading to adverse maternal and

neonatal outcomes. Women above a healthy weight preconception had the highest prevalence of excess GWG [7]. Lifestyle interventions prevent excess GWG and improve maternal and neonatal outcomes [8].

Australia's Clinical Practice Guidelines for Pregnancy Care recommend that at every antenatal appointment, women are given the opportunity to be weighed, discuss weight change, diet and level of physical activity [9]. In Australia, most women with obesity have antenatal care in a hospital setting. In antenatal care, regular weighing and information alone do not reduce excess GWG [10], and women need dedicated lifestyle intervention to support healthy lifestyle and improve GWG and health outcomes [11]. Pregnancy is a 'teachable moment', when women are more likely to be receptive to positive health behaviours [12,13]. Although studies show women are amenable to making changes in pregnancy, progress can be limited due to health professional barriers including time limitations, lack of training and reluctance to talk about the sensitive issue of gestational weight gain with women [14–16], as well as individual barriers of body image, family, work and knowledge [17,18].

In this context, The Healthy Pregnancy service was established in 2015 at Monash Health, the largest health service in Australia, to care for women with a pre-pregnancy BMI of ≥35 kg/m^2. This co-designed antenatal service is an embedded, evidence-based lifestyle intervention. It is based on the principles of the Healthy Lifestyle in Pregnancy Intervention (HeLPher) [19,20], shown to be effective in women at increased risk of gestational diabetes in routine antenatal care. The program is underpinned by goal setting, self-monitoring, social support and problem solving. The use of dedicated staff including physician (endocrinologist) and health coach to deliver the program addressed the barriers of time constraints and expertise of routine maternity health professionals. The program also created an environment where all health professionals in the service were facilitated to undertake conversations with women around healthy pregnancy with lifestyle advice. This lifestyle intervention program constitutes pragmatic implementation research, where evidence is generated in the context of usual clinical care [21–23].

Implementation research has identified 14 domains within the Theoretical Domains Framework (TDF) that are related to behaviour change, allowing for targeting of intervention to increase guideline implementation [24,25]. These domains have been used to understand midwives' [14,26] and general practitioners' [15] experience of GWG in pregnant women, but there are limited reports about the TDF domains in multidisciplinary service settings [27].

The aim of this study was to explore the experiences and perspectives of the health professionals working in the integrated antenatal clinic and Healthy Pregnancy service in order to understand the barriers and enablers to the provision of lifestyle change advice.

2. Experimental Section

2.1. Materials and Methods

2.1.1. Study Design

A qualitative approach assessed health professionals' experiences while working in the Healthy Pregnancy service. Data was collected via semi-structured interviews with questions based on the Theoretical Domains Framework (TDF) that explores barriers and enablers of behaviour change and implementation research methods [25] (Table 1). The consolidated criteria for reporting qualitative research (CROEQ) 32-item checklist was used in planning and reporting [28]. This study was approved by the Monash Health Ethics Committee.

Table 1. Semi-structured interviews questions mapped to TDF.

Domain	Question
Knowledge (All interviewees)	What do you know about the Healthy Pregnancy service?
	What is the purpose of the Healthy Pregnancy service?
	What is your understanding of how women are referred to the Healthy Pregnancy service?
Skills (Health professional interviewees—not the administration clerk)	When are you likely to talk about GWG with women?
	Do you initiate conversations about GWG with women or do they?
	If you notice increased GWG, do you ask women about it?
	If so, how do you go about this?
	Do you feel you are delivering GWG information consistently? Why/why not?
Social/professional role and identity (Health professional interviewees—not the administration clerk)	What do you see as your role in the Healthy Pregnancy service?
	Are discussions about GWG and healthy lifestyles within your professional role?
	Do you do anything different in this clinic compared to the other clinics you work at?
	Do you weight women or talk about weight with women them?
Beliefs about capabilities (Health professional interviewees—not the administration clerk)	Do you feel confident talking about GWG with women?
	Do you believe you have the skills to talk about GWG with women?
	Do you feel comfortable referring people to the clinic? Why/why not?
Beliefs about consequences (All interviewees)	Can you tell me about your thoughts about healthy weight gain in pregnancy? Is this a priority for you?
	What is your attitude to the Healthy Pregnancy service?
	Do you encourage women to go to the Healthy Pregnancy service?
	How do women receive the information you provide?
	What problems have you encountered within the Healthy Pregnancy service?
	Could you suggest any improvements to the Healthy Pregnancy service?
Environmental context and resources (All interviewees)	Do you communicate with other health care providers about GWG? How?
	There are fewer women being seen by the implementation team lately. Why do you think this is?
	Do you feel supported and valued as part of the Healthy Pregnancy service team?
Behavioural regulation (All interviewees)	What systems do you think are needed to improve the delivery of appropriate gestational weight gain advice to women?

2.1.2. Clinic Setting

This study is part of a broader pragmatic clinic trial (the Healthy Lifestyle in Pregnancy Project, HiPP) that evaluated the effect of a lifestyle intervention on gestational weight gain and maternal and infant outcomes in women with maternal obesity (Australian New Zealand Clinical Trials Registry: 12620000985987). The project was implemented within a large hospital network in metropolitan Melbourne, Australia, with approximately 10,000 live births per year [29]. Australia offers universal freely accessible health care and Monash Health is the largest health service nationally, situated in a low socio-economic status (SES), diverse ethnic background catchment [30]. The specific service

provided care to women with a BMI of 35–43 kg/m^2 with approximately 200 live births per year, in a collaborative care model with obstetricians and midwives.

The Healthy Pregnancy service embedded a patient-led behaviour change lifestyle intervention, based on principles of the effective Healthy Lifestyle in Pregnancy intervention (HeLPher) [31]. It is delivered by a health coach and a physician/endocrinologist (intervention staff) at five sessions integrated with routine pregnancy care. The intervention is underpinned by social cognitive theory and focuses on behaviour change and self-management of weight, healthy diet and exercise, with skills practiced in goal setting, problem solving and relapse prevention. The first intervention assessment coincided with the first medical review, typically scheduled between 12 and 18 weeks. Session 2 occurred between 20 and 22 weeks, session 3–28 weeks, session 4–32 weeks and session 5–36 weeks. The study design was cognisant of the clinical demands of midwives and obstetricians who are generally time-poor and lack the training to spend prolonged periods counselling women on healthy lifestyle [32]. Therefore, midwives and obstetricians (non-intervention staff) in the Healthy Pregnancy service did not deliver the behaviour change intervention, but were supportive of the program messages and reinforced this to women throughout. Midwives and obstetricians had the opportunity to liaise with the intervention staff about individual's progress.

In this particular health service in Australia, women with a BMI ≥ 35 kg/m^2 are required to have their pregnancy care in a hospital setting. Currently, there is no standard national clinical approach for weight management in pregnancy. In this service, our clinical model of care involved a physician in addition to maternity staff. This acted to streamline care within the service, with the physician having a dual role in delivering the intervention and treating any medical conditions that required specialist care (gestational diabetes, thyroid dysfunction).

Administration clerks (non-intervention staff) responsible for all maternity bookings identified eligible participants and booked them either into the Healthy Pregnancy service, or if the weekly booking exceeded capacity or the day of the service was inconvenient, women were booked to alternative services, which comprised the control group. During their first midwife appointment, the midwife briefly introduced the clinic concept and the additional embedded intervention sessions which were integrated into the standard appointment template. Women could also be referred by midwives from other clinics. The comparison group comprised women who received standard care with no embedded lifestyle intervention.

2.1.3. Participants and Recruitment

Participants were recruited by RG (a female clinician-researcher) in person or by email. Purposive sampling targeted multidisciplinary staff working in the service: clinic midwives, nurse unit managers, an obstetrician, physicians, health coach and an administration clerk. Only 2 staff members (midwives) declined the interview due to time restrictions. One of the obstetricians (JB) and the main health coach (CH) working in the service were not interviewed as they were researchers involved in this study. Many of the clinicians also worked in other maternity clinics within the service, caring for women with normal weight to obesity. Participants were asked to answer questions about their experience in the Healthy Pregnancy service only. Staff are collectively referred to as health professionals, any responses from the administration clerk will be explicitly labelled.

Semi-structured interviews were conducted over the phone or in person by two female clinician-researchers (RG and RW), both with postgraduate expertise in qualitative methods. RG worked in the clinic as an endocrinologist for 1 year prior to commencement of the research project and then ceased clinical work to focus on the research. RG chose not to interview the staff with whom she had an existing professional relationship. RW was not employed in the clinic and joined the project in a research capacity only. RG performed the midwife interviews and RW the remainder. Written informed consent was obtained from all participants prior to the interview. To ensure rigour in the interviewing process, the interviewers discussed progression of the interviews at several times throughout the process. The interviews were between 10 and 30 min in duration and conducted in

October and November 2019. Data from the interviews was audiotaped and transcribed verbatim by an independent transcribing service. Participant details were deidentified for anonymity. The facilitators modified the line of questioning according to answers for each domain. Interviews were collected until data saturation was reached, determined when no new ideas emerged from the interviews.

2.1.4. Data Analysis

All transcripts were independently analysed and coded by two researchers (RG and RW), using the NVivo 12 software (Nvivo (Version 12), QSR International Pty Ltd., Melbourne, Australia (2018)). Data was searched for concepts in relation to research questions. These were given code names, and code names were categorised according to the TDF in a deductive process of thematic analysis [25]. Codes related to one or more domains. Coding of three randomly selected transcripts were undertaken by the researchers (RG, RW). After cross-checking for consistency, all transcripts were coded before the authors met to finalise coding and agree on theme development.

3. Results

Women who attended the Healthy Pregnancy service between 2016 and 2018 were compared to standard care regarding the primary outcome of GWG and secondary maternal and infant outcomes [33]. Intervention uptake was 95%, and 87% of women attended 80% or more of the five sessions. Women's perspectives of the clinic were also gathered via qualitative interviews and questionnaires (data not presented here).

Overall, 14 female staff members participated in our study (demographics in Table 2): 7 midwives, 2 nurse unit managers, 1 obstetrician, 1 health coach, 2 physicians and 1 administration clerk.

Table 2. Demographic characteristics of interviewees.

Staff Member *	Position	Experience in this Clinic
Midwife	senior	#1 #3 #5: Significant
	senior	#2 #7: Limited
	junior	#6: Limited
	junior	#4: Some
Nurse unit manager (midwife)	senior	#1: Significant #2: Significant
Obstetrician	senior	Significant
Physician	senior	#1: Significant #2: Significant
Health coach	senior	6 months (maternity leave position)
Administration clerk	administration clerk	Significant

* All are female. Experience: significant, >3 years; some, 1–2 years; limited, <1 year. # The # signifies number, the midwives have been identified by a number in the quotes (eg midwife #3) for anonymity.

Health professionals' experiences of working in the Healthy Pregnancy service were related to six domains of the TDF: (1) social/professional role and identity, (2) skills, (3) beliefs about confidence, (4) emotions, (5) beliefs about consequences, and (6) environmental context and resources (Table 3). These themes and how they relate to the TDF are described with example quotes below.

Table 3. Themes and sub-themes mapped to TDF.

Themes and Sub-Themes	Barrier	Enabler	TDF Domain
THEME 1: Health professionals view themselves as part of team to support healthy lifestyle and GWG			
Sub-themes:			Social/professional role and identity
• Staff roles		+	
• Team work/communication between staff	+	+	
• Staff feedback		+	
THEME 2: Health professionals reported having skills to run a Healthy Pregnancy service			
Sub-themes:			Skills
• Open communication in describing the clinic to women		+	
• Develop rapport		+	
• Empowering women to be involved		+	
THEME 3: Experience generated confidence in discussing GWG	+	+	Beliefs about confidence
THEME 4: Health professionals want women to be comfortable in this service			
Sub-themes:			Emotions Behavioural regulation
• Women's reluctance to engage	+		
• Midwives' fear of upsetting women	+		
• Managing women's negative experience		+	
THEME 5: GWG is variably considered of importance among health professionals	+	+	Beliefs about consequences
THEME 6: The environmental context and resources presented some barriers			
Sub-themes:			Environmental context and resources
• Waiting time and clinic day unsuitable for women	+		
• Lack of awareness of Healthy Pregnancy service amongst some midwives	+		
• Improving patient resources		+	

The + corresponds to the sub-themes (whether they were barriers or enablers).

3.1. Theme 1. Health Professionals View Themselves as Part of Team to Support Healthy Lifestyle GWG

Health professionals perceive themselves as being part of a multidisciplinary team to promote healthy lifestyle behaviours, and recognise the importance of team work and reflection on feedback and achievements.

- Sub-theme: Staff roles

Midwives identified their roles as referring women to the Healthy Pregnancy service (from within the usual clinic channels or from other clinics), providing initial advice about healthy weight goals, regularly weighing women and supporting lifestyle goals developed with the health coach and physician, recognising that they do not have the time or expertise to deliver more detailed advice.

> "as a midwife I would, as I say, initially just refer them, and then throughout the midwife appointments I would just make sure that they are trying to stick to the diet plan that the . . . health coaches, have put in place" (Midwife #6, junior, limited experience in clinic)

> "weighing them throughout pregnancy we can, um, you know, just keep an eye on what their weight gain is and reinforce that advice depending on how they're going with their weight." (Nurse unit manager 1, senior midwife)

Nurse unit managers recognise their leadership role as helping the midwives identify women appropriate for the clinic.

> "we've done lots of education with our teams and our midwives that work in clinic that any patient that comes through that fits that criteria (for Healthy Pregnancy service) needs to be directed into that space." (Nurse unit manager 2, senior midwife)

- Sub-theme: Teamwork/Communication between staff

During the clinic, there is open communication between the health coach, physician, nurse unit manager and obstetrician as needed, regarding new referrals as they arise or complex women. Issues could arise at times as the obstetricians/midwives and the health coach/physicians use different electronic database systems for recording clinic notes and are not always able to access both. Junior midwives are more likely to address concerns with their nurse unit manager.

> I think that from an in-charge perspective we have really good relationships with the … physician and the health coach." (Nurse unit manager 2, senior midwife)

> "I think the health coach and the physician work very closely together. So in terms of the patient flow we were always sort of touching base during the clinic and just seeing where each other are at, who's seeing which patient. We even touch base about how the patients are going, if there's anything of note, so yeah. I feel very well supported." (Physician 2)

> "there is some sort of miscommunication using two different (electronic medical record) systems., so I'm still dependent on the obstetrician printing the notes and leaving that in the patient's obstetric folder, so that I can see what they've said, otherwise there's no way of knowing what they're doing." (Physician 1)

- Sub-theme: Staff feedback

Overall, the staff reported positive feelings about the clinic, and acknowledged teamwork and expertise as being the main enablers allowing the obstetricians and midwives to devote their time to other issues. Having the physicians on-site streamlined referrals. They were able to identify some success stories amongst the women that engaged in the service.

> "I think initially they (other staff) weren't sure about our role in the clinic but I think now they're absolutely delighted to not have to talk about all this stuff themselves. So I think they're actually very happy to have us there." (Physician 2)

Staff perceived that their interventions were making an impact on the women's pregnancy, with women taking on some of the goals discussed.

> "And a lot of women say "I wish I had this in my previous pregnancy". So most people are actually really open to it and, you know, I think you know get a lot of it." (Physician 2)

> "I think they, that most of the people actually took the advice on board and – especially when … we actually brought the gestational weight gain on a chart so that's … really good feedback for them as well so that they can actually see that their gestational weight gain is sort of off the chart, it becomes a really good." (Health coach)

> "I always think about one girl who...actually only gained six kilos in her whole pregnancy. Um, it wasn't stressful, there was no like pressure, it was just - just simple, just good education," (Midwife #3, senior, a lot of experience in clinic)

3.2. Theme 2. Health Professionals Reported Having Skills to Run a Healthy Pregnancy Service

Health professionals in the Healthy Pregnancy service (both intervention and non-intervention staff) believed they had the skills to meet the objectives of the clinic and provide the level of care required to meet women's needs. Key skill strengths included clearly describing the purpose of the clinic to women, developing rapport and supporting them to be involved in their goal setting.

- Sub-theme: Open communication in describing the clinic to women

Midwives felt that if they clearly explained the purpose of the Healthy Pregnancy service to women, then women would be more likely to approach it positively. In addition, most midwives explained that they weighed all women at every appointment, thereby normalising the process. Overall, midwives felt that they had good communication skills in explaining the service to women in an open, clear manner. The establishment of the service with specific goals has enabled conversation about weight gain.

> "They tend to be then more open when you tell them why you're doing it, that it's not just to be mean." (Midwife #5, senior, a lot of experience in clinic)

> "I think the fact that we ask to do a weight at every appointment can make it easier, because you're not just singling somebody out to do it. You're doing it for everyone." (Midwife #1, senior, a lot of experience in clinic)

> "it's really sort of legitimised in a lot of ways... I don't want to say the stigma, but it's made it easier to talk to these women about weight gain because they're going to—they're going—they're in that clinic for that purpose. So it does sort of make it a gentler introduction for me." (Obstetrician)

- Sub-theme: Develop rapport

Health professionals recognised that their skills in making women feel comfortable created an environment where women were more likely to talk about sensitive issues such as diet, weight and lifestyle and this was facilitated by ongoing relationships through the pregnancy. One midwife drew on her personal weight issues to relate to women.

> "we have a nice team involved. I think women are used to us just discussing it in a very, you know, sensitive non-judgemental way. So I think that helps." (Obstetrician)

> "if I get to know them I start building that rapport … they're happier to talk about it and they're happy to tell me about their diet and seek help" (Midwife #6, junior, limited experience in clinic)

- Sub-theme: Empowering women to develop healthy lifestyle behaviours

Intervention staff were able to use their coaching skills to help women set and achieve their behaviour-change goals, giving them an active role in decision making, rather than providing prescriptive advice.

> "focusing on … getting the people to come up with their own areas of improvement and setting their own goals. So it's more a patient-focused kind of approach." (Health coach)

> "To actually hold back and, and try and tease that out of the person instead and ask them … what they know about that area and what they think they should be doing. And more often than not, they actually do have a pretty good idea" (Health coach)

> "we … encourage the women to work out themselves, to work out new strategies to overcome those barriers and maybe new plans on how to achieve the goal" (Physician 1)

> Physician

3.3. Theme 3. Experience Generated Confidence in Discussing GWG

Confidence levels around discussing GWG varied significantly amongst the staff, with senior staff in the intervention team feeling confident to deliver their component of the program. Non-intervention staff would still discuss GWG with women, but in a supportive role, rather than in a delivery role. Junior midwifery staff, who may have less experience in discussing weight and weight gain, were less confident.

> Physician "I feel confident . . . I think because I've been working in that clinic for the last . . . three or four years. Like, I've worked in it since it started. So, um, I think just having to have those conversations with women." (Obstetrician)

> "a lot of our more junior staff would feel less . . . (confident)." (Midwife #2, senior, limited experience in clinic)

> "I wouldn't say I'm confident, but I do it because I know that women do need to know about it, yeah." (Midwife #6, junior, limited experience in clinic)

3.4. Theme 4. Health Professionals Want Women to Be Comfortable in This Service

Health professionals are aware of the sensitive nature of talking about obesity and weight gain. They are mindful of women's feelings and want to provide patient-centred care, offering care women need in a sensitive and non-confronting manner. At the same time, they recognise that some women with high BMI are reluctant to discuss their weight and at times will hold back in order to avoid conflict.

- Sub-theme: Women's reluctance to engage

Health professionals had realistic expectations about some women's reluctance to engage with the intervention sessions. The health coach and physician reported that some women are reluctant to engage if they are uncomfortable discussing their weight, or if they feel they have heard the advice in previous pregnancies and can manage on their own. In these cases, caregivers pull back and accept that engagement is optional.

> Physician

> "There is a small proportion of women who actually felt um, felt almost like she's been punished by being sent to this service . . . So none of them actually self-elect to be there and were simply um referred to this particular service because of their BMI . . . and there is that . . . almost animosity kind of attitude where, yeah. And I remember one woman in particular, she basically was just really unresponsive" (Health coach)

> "I do get some women who just for whatever reason have decided that that's not for them, um, and so I just address that with them and just make sure that they know what the clinic involves and then move on." (Obstetrician)

> "if they're really adamant (that they don't want to engage), like this is what I am and I don't care basically well then there is no point making a big issue out of it . . . because you just alienate the women and, um, it makes it harder to engage with them on other topics that are equally important, I guess." (Nurse unit manager 1, senior midwife)

- Sub-theme: Midwives' fear of upsetting women

The caregivers are fearful of causing distress to women, and need to balance being mindful of their feelings and delivering the health care they require. In these circumstances, the midwives will pull back.

> "Pregnancy's meant to be a nice, happy time, and I don't want them to think that I'm judging or - or you know, making judgments on their lifestyle". (Midwife #2, senior, limited experience in clinic)

> "It's also one of the most challenging things to talk about because, you know, people are sensitive about their weight and you, like you don't want to come across as though you are judging them, but it's being able to present it in terms of, um, being a desirable outcome without, like women feeling pressured about it, I guess". (Nurse unit manager 1, senior midwife)

- Sub-theme: Managing women's negative experience

A few women described negative experiences with attending the clinic. Senior staff took these criticisms on board, and using feedback and self-monitoring adjusted their behaviour.

> "from time to time women will come up and say "I don't want to make that appointment, I don't want to see them again", um, you know sometimes I've had a couple of women say "I'm fat, I know I'm fat, I've always been fat, nothing's going to change that, so I don't want to make a big deal of it", so "Okay, that's fine you don't have to see them if you don't want to". (Nurse unit manager 1, senior midwife)

> "Initially I, um, when I started the clinic I remember that there were a couple of women who were not very happy with … their first appointment with me … I asked them about … pre-existing weight, history of weight gain, these sort of things and, um, I kind of had a meeting with the health coach and we tried to rephrase, um, you know, those kind of critical questions and addressing their sensitivities, um, and that was it. Since then it's been all good. (Physician 1)

3.5. Theme 5. GWG Is Variably Considered of Importance among Health Professionals

Most of the health professionals viewed excess GWG as a priority in their clinical care. There was variation in the importance placed on maintaining appropriate GWG within the non-intervention senior staff, who at times may need to prioritise other medical problems encountered in pregnancy.

> "I know that that can impact more on their pregnancy and their risk of complications. Um, so it is a pretty high priority." (Midwife #1, senior, a lot of experience in clinic)

> "there's schools of thought on whether or not, you know, weighing women in pregnancy is of any benefit at all … and I know in the past we never used to do it … certainly knowing what the BMI is at the start of pregnancy is of use … I suppose it's a priority for me because Monash Health stipulates how we practice." (Nurse unit manager 2, senior midwife)

> "I generally tend to look at what—what their weight gain is and I will discuss it if it's excessive or if it's minimal but—no. It—it's not my be all and end all. I think foetal growth is far more important to me" (Obstetrician)

3.6. Theme 6. The Environmental Context and Resources Presented Some Barriers

The environmental context and resources were reported by health professionals as barriers to the Healthy Pregnancy service. For many women, the timing and wait time were inconvenient. Midwives also felt the pressure of inadequate time during consultations. As the service continued, midwife awareness of the service and subsequent referrals also declined.

- Sub-theme: Waiting time and clinic day unsuitable for women

One of the biggest barriers to engaging women in the service was the waiting time. At the initial appointment, women were required to see three clinicians: obstetrician/midwife, health coach and physician for a complete medical assessment and treatment plan (thereafter, intervention appointments were with usually either the health coach or the physician, at the clinicians' discretion). The computer booking system does not enable health professionals to know if a woman is in the waiting room or currently being seen by another clinician. As a result, occasionally women wait for longer than anticipated. This can lead to them leaving in frustration or because they have competing interests (e.g., a frequent issue was the need to pick up children from school). Nurse unit managers suggested that running a second clinic on a different day and in the morning may give greater flexibility and increase the number of women engaging in the service.

> "It's quite difficult to juggle because they're waiting around for the appointments, seeing a midwife and then the endo aren't sure if they've been seen—we haven't really figured out an easier way to facilitate that which is probably the biggest challenge that they're sometimes left waiting for quite a long time." (Midwife #7, senior, limited experience in clinic)

> "it's quite common that women will be part of the healthy lifestyle program and they'll come and they'll have their first appointment and things are running a bit late and they sit there and they haven't been seen yet and they'll come to the desk and say "Look I can't wait any longer I have to go", um, so that's yeah, I would say that's a significant barrier to women accessing the clinic" (Nurse unit manager 1, senior midwife)

Additionally, co-ordinating the bookings can be a challenge for administration. The administration clerk suggested changing the clinic codes may make bookings more streamlined.

> "it just is a matter of juggling, um, screens and going into different codes, going back and forth because I always make sure that the appointments are as close together as possible, understandably the women don't want to like come and see the midwife at 1.30pm and then not be able to get into the healthy lifestyle appointment till 3.30pm . . . but we can usually make it work." (Administration clerk).

- Sub-theme: Lack of awareness of Healthy Pregnancy service and content of clinic amongst some midwives

A number of midwives reported many new staff coming through the clinics, who may not be aware of the Service and therefore may not be referring women who are appropriate.

> "we've lost a lot of our more senior midwives, and not as many midwives are doing clinic. So we've got a lot more junior staff coming through...and we've got a lot of staff just being trained up and put in, so they're probably not aware of it." (Midwife #2, senior, limited experience in clinic)

More widespread awareness about the clinic to midwives working in other clinics was suggested to increase uptake. Midwives and the administration clerk expressed limited knowledge about the content delivered in the intervention, and showed interest in learning more so they can inform women.

> "I think probably every—start of every session people need to be reminded, BMI's over 35, off to healthy lifestyles". (Midwife #3, senior, a lot of experience in clinic)

> "maybe some more transparency to the rest of the staff about what they talk about and . . . running some education services or information in the tearoom so that, you know, for those women that aren't in the service the same kind of discussions can be held by other clinicians." (Obstetrician)

> "I'm just wondering if perhaps like the midwives could have some type of in-service as to being more educated on what the service offers . . . I wonder if it would be good to, yes sort of refresh them as to, um, yeah the service that's available." (Administration clerk)

- Sub-theme: Improving patient resources

Staff suggested providing more written resources for women about healthy weight gain, and putting educational information on the TV in the waiting room.

> "If we could get some written information for them as well but maybe something more comprehensive and, ah, most women use like different pregnancy applications, but you know, something more generic that we can, um, advise and like suggest to them and to download and use to track their weight gain. Um, something that could make it more visual and objective for them as well." (Physician 1)

> "Instead of just having midday TV running, maybe we could actually utilise that for education purposes. They might listen." (Midwife #5, senior, a lot of experience in clinic)

4. Discussion

This qualitative study evaluating health professionals experiences of the Healthy Lifestyle in Pregnancy Project (HiPP) identified six TDF domains that act as barriers or enablers for the implementation of this service—feeling part of team to support healthy lifestyle and gestational weight gain; having the required skills; experience generated confidence; variable importance of GWG to health professionals; wanting women to be comfortable in this service; and the environmental context and resources. Translation of these findings into practice is important to improve the implementation model and advance knowledge, clinician skills, confidence and resources.

There are a number of qualitative studies in the literature describing the experience of managing GWG in pregnancy for women across the BMI spectrum. However, the majority of these studies either survey midwives alone and/or describe the practice in routine antenatal clinics only [14,23,26,34]. The design of this study, however, is unique in that we describe an intervention embedded within routine care to limit GWG with dedicated intervention staff, and interview the full spectrum of health professionals. There are two studies that describe intervention models in this space: In Davis' Australian study [35], they offered a group-based intervention for women with a BMI > 25 kg/m^2 in antenatal care. However, this was facilitated by midwives, bringing in additional staff (dietician, physiotherapist) for specific sessions; only midwives are interviewed. In Jewell's UK study [17], women with a BMI > 30 kg/m^2 were offered weekly group-based sessions throughout pregnancy and up to 6 weeks postpartum with a midwife and a commercial weight management consultant; only pregnant women are interviewed. Our model was based on the recognition that those skilled in lifestyle intervention, including dieticians and exercise physiologists, are best placed to deliver these interventions. Hence, this service was delivered by a health coach and embedded alongside routine maternity care, and maternity health professionals reinforced the lifestyle intervention messages. In this way, women had the expertise they needed, without the need for additional appointments, whereas other studies did not have this service 'in-house' and its absence was noted [22,32]. To our knowledge, this is the only qualitative study describing such an intervention in a one-on-one setting in a multidisciplinary service.

Health professionals perceived themselves as being part of a multidisciplinary team and recognised the importance of team work and reflection on feedback and achievements. Understanding of staff roles and teamwork are factors that contribute to a cohesive workplace. Here there was clear awareness of staff roles, in contrast to other studies [27] where it was unclear who was responsible for managing weight in the context of shared maternity care, which can create confusion. Midwives and obstetricians are often not trained or supported with adequate time and resources for delivery [36]. This was relevant to the current clinic and hence, midwives and the obstetrician were appreciative of the lifestyle

implementation team's role to deliver an integrated intervention service and the maternity team were able to support women to maintain the plans developed by the health coach and physician.

Overall, staff displayed skills needed to run a Healthy Pregnancy service; they had open communication in describing the clinic to women, developed rapport in a non-judgemental way and encouraged them to be involved in decision making. The nature of the intervention being specifically designed for women with obesity meant that from the outset, the aims of the clinic were clear. As such, women were weighed regularly, in contrast to other studies [22,32,37], and staff were forthcoming with the measurements, unlike variable practice in a US study of midwives and obstetricians [38]. In this fashion, conversation around excess weight gain was already more acceptable among the staff, in contrast to a recent UK study, where conversation around weight was not yet normalised [27].

By interviewing a variety of health professionals, we were able to capture a broad perspective of the service. Confidence in discussing GWG and healthy lifestyle was high among the health coach and physicians given that they were delivering the intervention and developed sufficient experience during the time working in the service. Confidence among the midwives varied, with senior midwives expressing more confidence, in line with another Australian study describing confidence growing over time [35]. Lack of confidence voiced by junior midwives here is in keeping with other studies, due to inexperience communicating about excess weight [14,26,27]. Importance of GWG was viewed differently by health professionals; with the some of the senior staff (obstetrician, nurse unit managers) placing less of a priority on GWG than other staff members as they need to juggle other medical complications that arise.

Health professionals wanted women to be comfortable in this service. Staff members, midwives in particular were at times fearful of upsetting women when discussing the sensitive topic of GWG and obesity. This sentiment is echoed almost universally among health professionals [14,22,27,32,39–41], including the Australian intervention study of staff responsible for recruiting women into a similar new service model [35]. A probable contribution to this fear may be related to minimal undergraduate teaching in medicine and nursing, of skills related to weight gain conversations in pregnancy [15,42]. This view was not expressed by the intervention staff because they have more experience in dealing with this due to the nature of their roles; they are skilled with how to broach these conversations in a sensitive way that still enables rapport to be built. This has identified an area for further upskilling for all staff, in matters of dealing with sensitive issues (for fear of affecting relationships) and negative feedback.

We also identified some barriers in the environmental context that could be improved. Some newer booking staff members had less knowledge of the clinic and were referring less often; more regular education about the clinic would be of benefit. Non-intervention staff did express interest in learning more about what is implemented, which may in turn strengthen their support of the women, highlighting the need to keep them informed especially as new staff change over. In some situations, when staff members did not have access to the correct databases, communication between providers was not ideal. Staff reported a longer waiting time and clinic day being unsuitable for women as limiting factors in service uptake; this has been previously described [35] and needs to be addressed in future clinic design, with more options offered to women. Additionally, health professionals suggested improving patient resources, either in the form of electronic applications or information provided in the waiting room. This needs to be considered in the context of women's preferences, which will be analysed in a further stage of this project. However, it should be noted that feedback of these study findings to health professionals and women, and contributing to a co-design approach of future implementation may help overcome these barriers [43].

Strengths and Limitations

To the best of our knowledge, this is the only study that has evaluated a patient-led pragmatic intervention, delivered in the maternity setting and gaining perspective from staff members with different staff roles, allowing a more balanced perspective of the intervention. The findings gleaned have a key role in informing guideline implementation and scale up of interventions in this space. The study design was strengthened by the theoretical domain framework designed to explore guideline implementation [25]. The findings of this research will be strengthened when paired with

patient perspective. The results are limited by the participation of only one of the health coaches and obstetricians; the other clinicians were not interviewed as they were researchers in this study. RG's clinical experience may have influenced her interpretation of the participant's response. However, reflexivity was considered in the research process to increase rigour [44]. Additionally, this experience is of a single clinical service in one health service and will need to be interpreted with this in mind.

5. Conclusions

As excess GWG and obesity in pregnancy are prevalent and lifestyle intervention in antenatal care is effective, implementation knowledge is vital to inform and evaluate appropriate services aimed at improving outcomes. In this HiPP study, we have identified some barriers and enablers to the delivery and uptake of a lifestyle intervention, as perceived by health professionals. Translation of these findings into practice is important to improve the implementation model and advance knowledge, clinician skills, confidence and resources.

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3.4 Facilitators and barriers to behaviour change within a lifestyle program for women with obesity to prevent excess gestational weight gain: A mixed-methods evaluation

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Submitted Implementation Science

TITLE

Facilitators and Barriers to behaviour change within a lifestyle program for women with obesity to prevent excess gestational weight gain: A mixed methods evaluation

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Abstract

Background: Maternal obesity is associated with health risks for women and their babies and is exacerbated by excess gestational weight gain. The aim of this study was to describe women's experiences and perspectives in attending a Healthy Pregnancy Service designed to optimise healthy lifestyle and support recommended gestational weight gain for women with obesity.

Methods: An explanatory sequential mixed methods study design utlilised two questionnaires (completed in early and late pregnancy) to quantify feelings, motivation and satisfaction with the service, followed by semi-structured interviews that explored barriers and enablers of behaviour change. Data were analysed separately and then interpreted together.

Results: Overall, 49 women attending the service completed either questionnaire 1, 2 or both and were included in the analysis. Fourteen women were interviewed. Prior to pregnancy, many women had gained weight and attempted to lose weight independently, and reported they were highly motivated to achieve a healthy lifestyle. During pregnancy, diet changes were reported as easier to make and sustain than exercise changes. Satisfaction with the service was high. Key factors identified in qualitative analysis were: service support enabled change; motivation to change behaviour, social support, barriers to making change (intrinsic, extrinsic and clinic-related), post-partum lifestyle and needs. On triangulation of data, qualitative and quantitative findings aligned.

Conclusions: The Healthy Pregnancy service was valued by women. Barriers and enablers to the delivery of an integrated model of maternity care that supported healthy lifestyle and recommended gestational weight gain were identified. These findings have informed and improved implementation and further scale up of this successful service model integrating healthy lifestyle into routine antenatal care of women with obesity.

Keywords: gestational weight gain, obesity, health coach, intervention, implementation, qualitative, health professionals, pregnant women, mixed methods

Registration

This trial is registered with the Australian New Zealand Clinical Trials Registry (no.12620000985987). Registration date 30/09/2020, retrospectively registered. http://www.anzctr.org.au/

Contribution to literature

- Randomised controlled trials designed to improve healthy lifestyle, limit gestational weight gain and improve maternal and infant outcomes are effective. The priority and remaining challenge is to implement these programs into usual maternal care
- Successful programs require dedicated, well-trained health professionals that can educate, empower and support women to make changes
- This mixed-methods study identifies barriers and enablers to the delivery of an integrated model of maternity care. These findings contribute to gaps in the literature and will inform and improve implementation and further scale-up of this successful service model

Background

Maternal obesity and excessive gestational weight gain (GWG) both independently contribute to adverse maternal and neonatal outcomes (1, 2), as well as to increased risk of postpartum obesity development in mothers and their children (3, 4). The National Academy of Medicine (previously Institute of Medicine, IOM) recommendations for healthy GWG are specific to a woman's pre-pregnancy BMI (5). A systematic review and meta-analysis (6) of more than one million women demonstrated that almost half gained above GWG recommendations leading

to adverse maternal and neonatal outcomes. Women above a healthy weight preconception had the highest prevalence of excess GWG (7).

Pregnancy has long been considered ‘a teachable moment’ for optimised weight gain and obesity prevention (8). Interventions designed to improve healthy lifestyle, limit gestational weight gain and improve maternal and infant outcomes are effective, supported by level I evidence (9). The priority and remaining challenge is to implement these programs into usual maternal care (10, 11). Successful programs require dedicated, well-trained health professionals that can educate, empower and support women to make changes (12). Barriers include antenatal health professionals lack of skills, time and confidence discussing sensitive issues (13-15), and women can feel stigmatised if staff are not well trained (16). Generally, women are motivated to make positive changes, but want support and direction from qualified health professionals (17, 18).

The Healthy Pregnancy service was established in 2015 at Monash Health, the largest health service in Australia, to care for women with a pre-pregnancy BMI of ≥35 kg/m². This co-designed antenatal service integrates an embedded, evidence-based lifestyle intervention, the HeLP-her Healthy Lifestyle in Pregnancy Intervention (19). The HeLP-her program intervention has been shown to be effective in reproductive aged women in multiple settings outside of pregnancy as well as in pregnancy, including women at increased risk of gestational diabetes in routine antenatal care (20-23). It is also cost effective (24).The program is underpinned theoretically by The Social Cognitive Theory and promotes goal setting, self-monitoring, social support and problem solving (22). Here, in women with obesity at high risk of pregnancy complications, dedicated staff including a physician (endocrinologist) and health coach delivered the program, designed to address the barriers of time constraints and expertise of routine maternity health professionals. This model of care project was designed to incorporate pragmatic implementation research, where evidence is generated in the context of usual clinical care (13, 25, 26).

Mixed methods approaches in implementation research apply both quantitative and qualitative approaches with data triangulation to provide novel insights on implementation of models of care (27, 28). Here, the aim of this study was to apply mixed methods to explore the experiences and perspectives of the women attending the integrated antenatal clinic and Healthy Pregnancy service, to understand the barriers and enablers to lifestyle change and to identify how this service can be improved to inform sustainable implementation and scale-up.

Methods

Study Design

An explanatory sequential mixed methods study design was used (27). This two-phase design involved using two questionnaires completed by pregnant women at different time points during pregnancy, followed by qualitative interviews. Using this approach, the qualitative results aimed to expand and confirm findings from the quantitative phase and data was triangulated in analysis. The consolidated criteria for reporting qualitative research (COREQ) 32-item checklist was used in planning and reporting (29). This study was approved by the Monash Health Ethics committee.

Service setting

This study is part of a broader pragmatic implementation trial (The Healthy Lifestyle in Pregnancy Project, HiPP) that evaluated the effect of a lifestyle intervention on gestational weight gain and maternal and infant outcomes in women with maternal obesity (Australian New Zealand Clinical Trials Registry: 12620000985987). The project was implemented within a large hospital network in metropolitan Melbourne, Australia, with approximately 10,000 live births per year . Australia offers universal freely accessible healthcare and Monash Health is the largest health service nationally, situated in a catchment with a low socio-economic status (SES), diverse ethnic background population (30). The specific service provided care to women with a BMI of 35-43 kg/m² with around 200 live births per year.

The Healthy Pregnancy service embedded a patient-led behaviour change lifestyle intervention delivered by a health Coach and a physician (intervention staff) over five sessions integrated with routine pregnancy care. The physician also managed medical complications in pregnancy including gestational diabetes. The study design was cognisant of the clinical demands of midwives and obstetricians who are generally time-poor and lack the training and confidence to spend prolonged periods counselling women on healthy lifestyle (31). Therefore, midwives and obstetricians in the Healthy Pregnancy service did not deliver the behaviour change intervention, but were part of the team and were supportive of the program messages and reinforced this with women throughout.

Women who attended the Healthy Pregnancy service between 2016 and 2018 were compared to standard care (those not receiving embedded lifestyle intervention) for the primary outcome of GWG and secondary outcome of maternal and infant outcomes and implementation knowledge (32). Detailed study design is described previously: the first intervention session coincided with the first medical review, typically between 12-18 weeks, and final session at ~36 weeks. Intervention uptake was 95%, and 87% of women attended 80% or more of the 5 sessions. Health professionals' perspectives of the service also studied (12).

Questionnaire design

Questionnaires were developed to understand pregnant women's experience in attending the service to identify barriers and enablers to behaviour change. They were based on priori questionnaires used in an observational study among women with gestational diabetes mellitus (33), and in randomised controlled trial (RCTs) to limit gestational weight gain (22, 23, 34), and in self-management strategies using an adapted tool by Saelens (35).

Questionnaire one was completed at the first (or close to) the initial session (12-18 weeks). Questions assessed demographics, basic diet and physical activity, risk perception, motivation and readiness to change and self-management strategies. Questionnaire two was completed

at (or just after) the final session (36 weeks). Questions assessed satisfaction with service, changes made in pregnancy and corresponding barriers, and self-management strategies.

Some questions included a statement (e.g. I think it is important to have a healthy lifestyle during pregnancy) with responses on a 5-point Likert scale. In keeping with a pragmatic clinic trial approach, we did not intend for all women at the Healthy Pregnancy Service to complete the questionnaires, but rather a percentage of these. Questionnaires were initially distributed by mail in early 2017; between April 2017 and February 2018, the questionnaires were distributed in person by a researcher/clinician at the Healthy Pregnancy Service and completed in the clinic. Questionnaire 1 and 2 are in the Additional files 1 and 2.

Qualitative Interviews

Semi-structured interviews (Additional file 3) were conducted with a sample of women attending clinic to gain a deeper understanding of women's experience attending the service, and the barriers and enablers to behaviour change. Purposive sampling targeted women who were more than 31-32 weeks gestation, were representative of parous and nulliparous as well as those with and without GDM, and would have attended a substantial proportion of their intervention care. Women were not required to have completed the questionnaires. Questions were developed based on a preliminary analysis of the questionnaires. Participants were recruited by RG (a female clinician-researcher) in person. Interviews were conducted over the phone by RG, who had postgraduate expertise in qualitative methods. RG worked in the clinic as a physician for 1 year prior to commencement of the research project and then ceased clinical work to focus on the research. Written informed consent was obtained from all participants prior to the interview. The interviews were between 10-25 minutes duration and conducted in July and August 2017. Data from the interviews was audiotaped and transcribed verbatim by an independent transcribing service. Participant details were deidentified for anonymity. Interviews were collected until data saturation was reached, determined when no new ideas emerged from the interviews.

Data analyses

Quantitative and qualitative analyses were performed separately, with key findings integrated at the reporting level, as is typical of explanatory sequential mixed-methods design (27).

Quantitative data: analysed using STATA software, version 15.0. Categorical data were presented as frequency and percentage (n (%)). Continuous data were presented as mean (standard deviation). Responses to 5-point Likert-scaled questions (e.g. strongly agree, agree, somewhat agree, disagree, strongly disagree; or daily, weekly, monthly, occasionally, never; or always, very often, often, occasionally, never) were collapsed into 2 categories (agree/disagree; or regularly/rarely; or often/rarely) respectively. Mann Whitney test (Wilcoxon signed-rank) was used to compare responses to questions repeated in questionnaire 1 and 2.

Qualitative data: transcripts were independently analysed and coded by two researchers (RG and CL) using the NVivo 12 software (QSR International Pty Ltd. 2018). Data was searched for concepts in relation to interview questions. Codes were grouped into themes using inductive analysis to meet the aims of the study, in a constant comparative manner using a generic approach as described by Patton (36) and Harding (37). Consensus regarding the emerging themes was reached between the two researchers.

Results

QUANTITATIVE PHASE

Questionnaires were initially distributed by mail in early 2017, however the response rate was poor (14%). Between April 2017 and February 2018, the questionnaires were distributed in person and completed in the clinic (96% response rate).

Of the 157 women attending the lifestyle intervention between 2016 and 2018, 58 women completed either questionnaire 1, 2 or both. After excluding 9 women (either did not attend

lifestyle intervention clinic, BMI outside of range, moved to another health service), 49 women were included in the analysis: 44 completed questionnaire 1, 40 completed questionnaire 2 and 35 completed both questionnaire 1 and 2. The demographics of questionnaire 1 participants are shown in Table 1.

Questionnaire 1

Table 1. Demographics of questionnaire 1 participants (n=44)

Demographic	mean (SD) or no. (%)
Age (years)	29.6 (4.7)
BMI (kg/m²)	38.5 (2.1)
Parity	
0	22 (50)
1	12 (27)
2	7 (16)
3	2 (5)
4	1 (2)
Highest level of schooling	
year 10/11	9 (20)
year 12	10 (22)
post school certificate/diploma	15 (34)
bachelor degree and above	10 (22)
Employment	
full time	16 (36)
Part time/casual	15 (34)
no paid work	13 (30)
Average yearly income	
< $40,000	10 (24)
41-64,000	11 (27)
65-80,000	7 (17)
>81,000	15 (33)
GDM	
yes	15 (34)
no	29 (66)
total GWG (kg)	6.46 (4.4)

Weight and lifestyle

In early pregnancy, 21 (48%) of women reported weighing themselves regularly and 23 (52%) rarely. 31 (70%) had gained weight in the past year before pregnancy: 9 (28%) ≤4kg, 6 (19%) 5kg, 14 (44%) 6-10kg and 3 (9%) >10kg.

Prior to pregnancy, 38 (80%) had attempted weight loss in the last year, and 14 (32%) had consulted a health professional to manage their weight. To improve their lifestyle, 17 (39%) reported increasing vigorous exercise, 33 (75%) reduced portion size and 33 (75%) reduced snack foods/takeaway.

Before pregnancy, 38 (86%) were dissatisfied with their weight and 29 (89%) were dissatisfied with their body shape.

Risk perceptions, health beliefs, stage of change

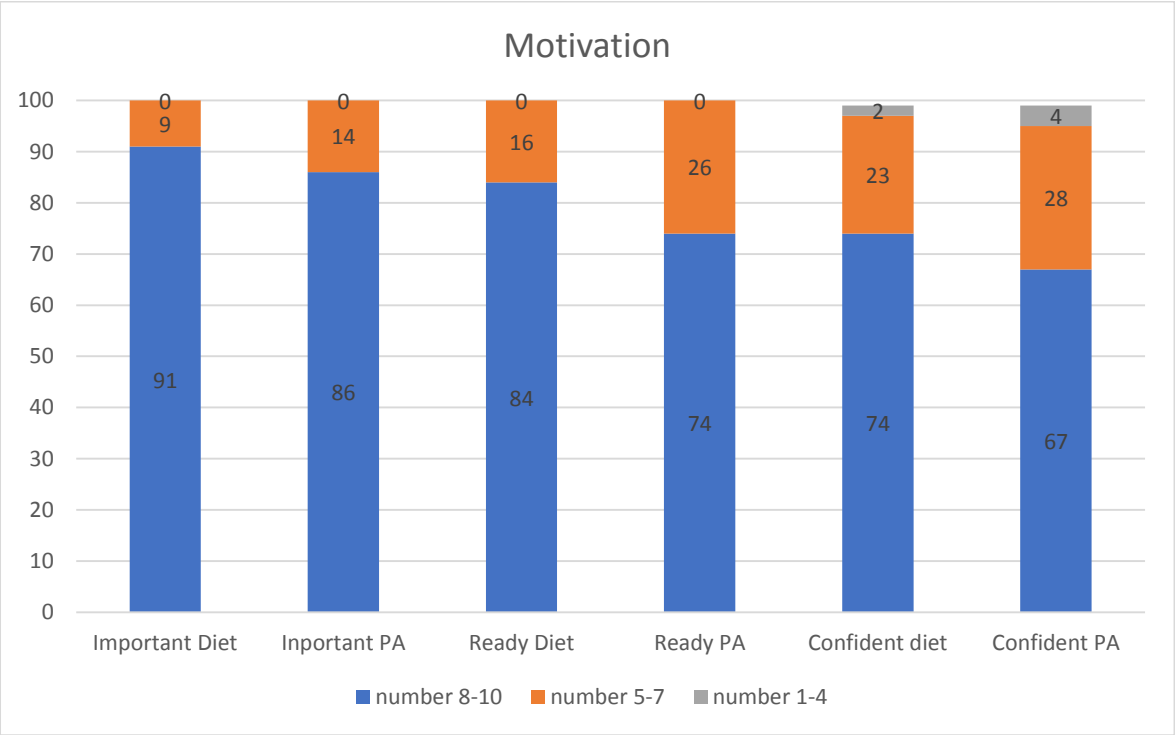
Twenty-seven (63%) women identified that 5-9kg is the ideal weight gain in pregnancy (consistent with guideline recommendations), 14 (33%) thought 0-5kg was appropriate. Twenty-six (65%) recognised that increased weight gain was not associated with more nutrients for the baby, whereas increased weight was reported as associated with big babies/macrosomia (17 (41%)), diabetes in pregnancy/gestational diabetes (25 (61%)) and high blood pressure in pregnancy (14 (34%)).

Early in pregnancy, 42 (95%) agreed that a healthy lifestyle in pregnancy is important and 37 (84%) thought they were at risk of excess weight gain, whilst 43 (100%) believed they could manage healthy lifestyle and weight gain in pregnancy, and 43 (97%) intended to take actions to prevent excess weight gain.

Readiness to change

Motivation was assessed in figure 1. Participants rated importance/readiness/confidence in making healthy lifestyle changes during pregnancy regarding diet/physical activity (PA), and responses were on a scale of 0-10 (0 not at all, to completely 10).

Figure 1. Motivation



Questionnaire 2

Satisfaction with the Healthy Pregnancy Service

This is described in figure 2. Participants rated their satisfaction with information provided by the antenatal team and their relationship with the health professionals. Women were very satisfied with the service, with 88% reporting satisfaction within information provided about healthy lifestyle and 90% reporting involvement in decision making.

Figure 2. Satisfaction with service

Changes made during pregnancy

Overall, 34 (87%) of women reported taking actions during pregnancy to achieve a healthy lifestyle, with the main changes being increasing water (26 (66%)) and fruit and vegetables (23 (59%)), and reducing takeaway (20 (51%)). Less women made changes to physical activity, with increased number of exercise sessions (14 (36%)) and increased time on sessions (3(8%)).

Maintaining change

Overall, 24 (65%) worked on maintaining changes to diet and 19 (51%) worked on maintaining changes to physical activity, whilst 28 (74%) were confident they could maintain lifestyle changes post-partum.

Barriers to lifestyle change

Women reported fatigue as the main barriers to lifestyle change (32 (82%)), followed by lack of time (18 (46%)), taking care of other children (14 (36%)) and no motivation (10 (26%)).

Comparison of questionnaire 1 and 2

Selected responses to a 29 question survey of self-management strategies based on an adapted tool by Saelens (35) completed early and late in pregnancy are compared in Table 2. Over the course of pregnancy, women reported a significant change in some behaviours around food: describing making time to prepare healthy meals, having quick healthy food available, trying new recipes and replacing snacks with healthier choices. They also reported weighing themselves more regularly.

Table 2. Self-management strategies

	Frequency	Questionnaire 1 n (%)	Questionnaire 2 n (%)	Comparison Mann- Whitney (p-value)
PHYSICAL ACTIVITY (PA)				
Think about benefits from PA	Often	33 (75)	32 (80)	0.53
I know when I should do more	Often	36 (82)	31 (79)	1.00
Plan ahead of time	Often	35 (57)	23 (58)	0.71
Stick to my plans	Often	26 (59)	23 (58)	0.52
Make backup plans to get PA	Often	14 (32)	11 (28)	1.00
Keep track of PA	Often	18 (41)	18 (46)	0.53
Able to get back on track when off-track	Often	19 (43)	21 (53)	0.21
DIET				
Watch what I eat	Often	32 (74)	30 (77)	0.74
Keep track of diet	Often	24 (55)	26 (67)	0.10
If don't eat well, think about ways to improve	Often	27 (61)	28 (72)	0.16
Make time to prepare healthy meals	Often	19 (43)	27 (69)	0.004
Have quick healthy food available	Often	22 (51)	29 (76)	0.01
Try new healthy foods and recipes	Often	22 (52)	30 (74)	0.02
Eat healthy food	Often	30 (68)	31 (79)	0.10
Replace snacks with healthier choice	Often	24 (56)	29 (74)	0.008
WEIGHT				
I watch my weight	Often	27 (61)	27 (69)	0.21
I weigh myself regularly	Often	20 (45)	20 (51)	0.008

QUALITATIVE PHASE

Fourteen women agreed to participate in an interview and all were interviewed. Women were a mix of nulliparous and parous, with and without GDM, and most had completed some post school education and were employed. The demographics of interview participants are shown in Table 3.

Table 3. Demographics of interview participants (n=14)

Participant no	***Age***	***Gestation***	***Parity***	***GDM***	***Pre-pregnancy BMI (kg/m²)***	***total GWG (kg)***	***Highest level of schooling***	***Work***	***Income***
1	*24*	*36*	*0*	*no*	*36.9*	*7.3*	*post school certificate*	*full time*	*$65-80,000*
2	*35*	*33*	*1*	*no*	*39*	*9.7*	*post school certificate*	*part-time*	*$>81,000*
3	*24*	*34*	*0*	*no*	*38.2*	*9*	*year 11*	*no paid work*	*<$40,000*
4	*31*	*34*	*0*	*no*	*38.7*	*5.6*	*bachelor degree*	*full time*	*$>81,000*
5	*38*	*31*	*2*	*no*	*41.3*	*2.5*	*bachelor degree*	*part-time*	*$65-80,000*
6	*27*	*32*	*0*	*no*	*42*	*10.2*	*bachelor degree*	*full time*	*>$81,000*
7	*24*	*31*	*1*	*no*	*42*	*3.6*	*year 12*	*part-time*	*>$81,000*
8	*25*	*34*	*2*	*no*	*39.7*	*8.4*	*year 10*	*no paid work*	*$65-80,000*
9	*30*	*31*	*0*	*no*	*37.6*	*12.1*	*bachelor degree*	*part-time*	*$41-64,000*
10	*31*	*34*	*0*	*yes*	*35.4*	*-2.5*	*post school certificate*	*casual*	*>$81,000*
11	*35*	*32*	*0*	*yes*	*42*	*3.8*	*post school certificate*	*full time*	*>$81,000*
12	*33*	*37*	*2*	*yes*	*36*	*8*	*post school certificate*	*full time*	*>$81,000*
13	*26*	*36*	*1*	*yes*	*36.2*	*14.4*	*post school certificate*	*no paid work*	*$41-64,000*
14	*25*	*36*	*0*	*no*	*36.9*	*10.3*	*year 12*	*part-time*	*<$40,000*

Interview themes are summarised in table 4 and described with example quotes below.

Table 4. Themes and subthemes

Themes and sub-themes	Barrier	Enabler
THEME 1. Service support enabled change Subthemes • Rapport with staff • Advice provided • Awareness created change		 + + +
THEME 2. Drivers of motivation to behaviour change Subthemes • Women's own motivation • Potential health consequences • Being accountable to healthcare professionals	 +	 + + +
THEME 3. Social support		+
THEME 4. Barriers to making change • Personal: intrinsic and extrinsic • Clinic-related	 + +	
THEME 5. Post-partum lifestyle and needs • Sustainable lifestyle changes • Support required to maintain lifestyle changes	 +	 + +

THEME 1. Service support enabled change

Most women felt that the service and the intervention staff (health coach and physician) enabled positive behaviour changes. Key strengths included developing rapport, delivering clear advice and providing awareness that created change.

- Sub-theme: Rapport with women

Women described the intervention staff as interested in their well-being and acknowledged the comfortable environment created. Staff involved them in decision making and supported the decisions women made.

"compared to other doctors, that they were really interested in what you have to say. They gave honest opinions, and feedbacks, um, which I really liked as well... I felt like very comfortable when I was talking to everyone, so, um, yeah, it was a very… it's a very positive experience going through that clinic". (participant #1)

"they would always asked me those questions. "Are you still going through those issues? Do you want to try and, um, find another… another solution? Um, do you want to try and take another approach?" … I was very pleased…they weren't pushing or pressuring, or anything. So they weren't persistent. Um, which is also good because you can't really pressure someone into doing things" (participant #1)

- Sub-theme: Advice provided

Women reported receiving clear information around diet, exercise and weighing goals that was easy to take on board and felt the level of support helped them make changes. The intervention team had realistic expectations of achievable goals and provided personalised advice.

"I've obviously got restrictions on what I can do because I've got other health concerns but um they tried to work around that, you know, with things that I obviously do – can do, so like swimming and stuff like that. They were very encouraging about participating in those." (participant #4)

"Exercise has been restricted for me, because I had a subchorionic haemorrhage earlier on, and the blood clot still hasn't absorbed. So I've been put on exercise restrictions, but they

were really good with giving me exercises that I am allowed to do. Like walking, and um, the physician even suggested like sometimes while I'm sitting down watching TV, just to have like, light two kilo dumbbells, and just to be using them with my arms. Um, just to be like, burning a few excess calories without putting anything at risk. Um, so I found that really helpful." (participant #7)

"I found it really helpful that she tracked my weight because I don't do that very well. So I can see through her that, you know, my weight is increasing dramatically or if it's slowing down… I like being able to see data and having that presented to me kind of changes my mind and changes my opinion a lot and from that I can then go and do things" (participant #9)

- Sub-theme: Awareness created change and improved satisfaction

Women were able to identify changes that they made after planning with the intervention staff, and a number reported feeling more confident as a result of making changes.

"I was more aware of what I was eating and portions. I find that when you buy food out as well, the portions are way too big…my biggest example just the other day was I got one of those boxes of noodles that you get…and it's probably three servings. I didn't realise that…but when I put it in a bowl out of the box – it changes everything" (participant #4)

"one of my cravings was ice cream and they told me to substitute it for frozen yogurt if I could. So I did that, and then the craving for ice cream kind of went away. So I cut that out as well. Also with like milk and cheese, they just said to choose the light option if I could, if I didn't mind the flavour and stuff like that. So I tried that as well and that was good." (participant #3)

"I never had a health coach with my first or second, and I wish I did. So with my first… I put on 36 kilos. With my second I put on 19. I'm now on my third, and I've only put on seven. So

I wish that back then, when I did have my daughter, and put on 36 kilos, that there was a health coach to show me the rights and wrongs." (participant #7)

THEME 2. Drivers of motivation to behaviour change

Women described different drivers to making behaviour change, depending on their personal experience.

- Subtheme: Women's own motivation

Those with previous pregnancies or better health literacy came in with more experience and were able to implement changes more independently, sometimes initiating changes before attending the clinic. Some women described their motivation as being intrinsic.

"I was very confident to start with because it's not my first. So having already had two kids, this is sort of routine. I kind of know what to expect and what's coming and all of that sort of thing. So yeah, I was fairly confident to start with. Um, seeing them each time and, you know, getting weighed and knowing that I'm definitely doing the right thing, that helped" (participant #5)

"knowing that I was pregnant and that I had gestational diabetes (previously), and the chances of me having it again was higher, so making sure that we push forward with changing our diet early on." (participant #12)

"all of these (changes) were up to me and it was up to me to make them work. I could gore down a whole pack of doughnuts if I wanted to but it was about controlling it. So I would be the one that would hold myself back if I slipped." (participant 4)

- Sub-theme: Potential health consequences for baby

Women were motivated to make changes, believing that this impacted the health of their child. These feelings were heightened if they developed a complication in pregnancy, with an awareness that lack of action could affect the baby.

"it was more that I was aware that it wasn't just my own health that I was impacting, it was also the baby's, so I had to do these things to give him the best possible chance." (participant #4)

"when I found out I had the diabetes. I made really big changes... when it was, you know, for a reason, it was like, "Yeah, I really do need to change that. And I can swap that; it's that easy. I can swap that." (participant #8)

"at the start of my pregnancy like I came back…I did Down Syndrome test, and it came back as a high risk. And then that kind of you know - and I just wanted to take care of my baby throughout this pregnancy. Like it was, it was a lot different to my first one." (participant #13)

"I was a little bit fearful, and that's why I found I had to make those changes." (participant #11)

Very few women identified talking about their weight as a sensitive issue and a potential barrier. Most women had a practical attitude towards discussing their weight, and saw this as a necessary step in making change.

"I've always been a bit chubby…and I used to be very sensitive about it but I'm kind of like past that point now so it's more… now that I'm pregnant, I wanted to be as healthy as I can possibly be…I knew that they were there to help basically so I just thought the best thing is to be as honest as possible rather than hide things." (participant #14)

- Sub-theme: Being accountable to healthcare professionals

Many women found the regular appointments with the intervention staff to check on their progress as a technique for keeping on track. In contrast, a small number of women described fear of disapproval from the staff for not meeting goals as a barrier.

"I did find the accountability very helpful, um, someone actually checking up on me and making sure I'm staying on track and I'm doing the right thing." (participant #14)

"sometimes I would fall back into my old ways, and it would encourage me to you know like - she would like encourage me to do like better, and you know eat the proper foods, and exercise a bit more. Yeah. She was good". (participant #13)

"sometimes I was really nervous that I was going to go in there and they would be like, "Oh no, you're putting on too much weight" or something like that and I was a little bit worried about that because I know that they weigh me and, you know, those are always really nervous times" (participant #4)

THEME 3. Social support

A number of women were very open with their family about lifestyle change, and in return received moral support from their family, their partner in particular.

"I had that support from my husband, because you know, he does come around with me on these walks, so he's, um, a bit more encouraging with that. So you know, he said, "if you can't do half an hour, we'll walk for 20 minutes now, and then in an hour's time, we'll walk another 20 minutes or so." (participant #1)

"my mum's been doing it with me, so that's good…and my dad's been really good with watching my daughter and stuff when we go out, and you know, if we can't take her with us...

Um, so yeah, I mean, they've been really supportive in the fact that I need to do the… you know, the extra exercise" (participant #7)

In some circumstances, women's changes had a positive flow on affect to other family members.

"my mother, um, she's started buying things that, you know, that I …wouldn't have eaten before. So she'll have skinny milk in the fridge if I come over and things like that" (participant #4)

"And my husband's been fantastic. He's changed uh pretty much a lot of the things that he eats himself to support me. So we don't have white bread in the house anymore. We have seeded bread and things like that. So um yeah, my family and friends have been fantastic. My husband is exercising much more now as well. Um, so he's uh more aware of himself in general. It's good." (participant #4)

"my husband is very supportive of healthy eating. He wants us all to be healthy. Um, friends are fairly supportive. They've been coming swimming with me and yeah, yeah, my husband has also been coming swimming with me recently. Yeah, it's been good." (participant #9)

THEME 4. Barriers to making change

A number of barriers to making change were identified, being intrinsic, extrinsic, and clinic-related.

- Sub-theme: Intrinsic

Intrinsic limitations for making change related to fatigue, medical problems, self-control and sensitivity discussing their weight.

“there are days where I’m just so exhausted. I’m like, “Oh my god, I just want to skip it”, but I know that I really shouldn’t” (participant #7)

“I started going for walks like for about half an hour to 40 minutes a few times a week. But that stopped a little bit later, just due to pelvic pain and stuff like that. So I've just been doing shorter walks and getting in as much activity as I can.” (participant #3)

“making the changes can be really hard, definitely being pregnant. So when you want something, you want to eat that, it’s like, “Oh no, sorry, you can’t.” I’ve got to go home instead, and make a sandwich” (participant #8)

- Sub-theme: Extrinsic

External barriers related to time, inclement weather, work, other children and finances.

“my time constraints with my work schedule, so it wasn't anything that could really change… because I work shift work… my meal times would be different throughout the day. So sometimes because I would be at work I wouldn't have time to have a snack when I should have had a snack.” (participant #6)

“I was overloading (at university) and then I went away and did placement. So um that was stress and yeah, that was a barrier to making changes and then after that was finished, I kind of was able to make changes and I had the energy to make changes” (participant #9)

“my 18 month old daughter really… with the exercise and that… but it's just with her, having her as well. Like it's been quite difficult to be able to get outside.” (participant #13)

“Cost is always a factor, especially healthy food seems to be more expensive than junk food, which is really a pain. I’m like, “I love capsicums but they’re so expensive.” (participant #9)

- Sub-theme: Clinic-related

Some women commented that their relationship with healthcare professionals made them feel somewhat uncomfortable initially. Some women acknowledged this may be due to their underlying sensitivity about their weight and felt that staff may have had preconceived ideas about women's lifestyle.

"I felt a bit judged…I felt that she just wanted me in, and just wanted me out. She didn't smile." (participant #8)

"the physician – she was a bit, I don't know, distant, I guess. I found it a little bit difficult to kind of connect with her…I felt like I could make a decision if I wanted but um she was a bit resistant to what I was telling her to a certain extent, like her listening skills weren't as good as they should be…it was probably just that I didn't really click with her when I first met her but, you know, after that I kind of figured out how to kind of get the information that I wanted." (participant #9)

"I know this is very much my perception of it, and it wasn't ever intended - but it was very much because you're obese, and you've got a high BMI, you're going to be higher risk for gestational diabetes, and blah, blah, blah. But they were saying all that before they knew that my diet and my exercise were actually quite good and I didn't need to change my diet… So I just - I kind of felt personally that they kind of assumed that you're going to have issues with trying to change your diet and all that sort of stuff." (participant #6)

Women commented on the waiting time, the fact that the clinic only ran on one particular weekday, and the parking expense as barriers.

"it was only Wednesday afternoon from one o'clock onwards that it was available. It didn't offer a lot of flexibility" (participant #2)

"pay for parking is a bit dear, next door… and just the waiting time sometimes. Like, not all the time, but the waiting time is a burden" (participant #1)

THEME 5. Post-partum lifestyle and needs

- Sub-theme: Sustainable lifestyle changes

Women were able to identify lifestyle changes that could be sustained post-partum. Most felt that diet changes were more achievable than exercise, and recognised that intensity of changes may be reduced compared to pregnancy. Women without children were less confident in their ability to find time to exercise.

"for sure…getting out of the house with a newborn is the best thing for you in terms of, you know, not getting depression and whatnot, which I experienced last time." (participant #7)

"the food changes, the majority of the time I can keep up but it would probably be like less um – it won't be as full on as it is now…I'll be like a bit more relaxed about it definitely." (participant #14)

"the main change was the eating habits and that sort of thing and they've pretty much stuck now so I'll keep going the way I am." (participant #5)

"I hope that once the baby is born, I will stop being in pain and it'll be easier to cook um and maintain like a good balance of meat and veggies and carbohydrates in my diet…hopefully I'll be able to go back to walking the dogs." (participant #9)

So I think um I would like to increase my exercise, again more once I'm not pregnant. The only difficulty will be that we'll be trying to do it with a newborn… it will just be once again like finding time to do - go food shopping, and meal preps, and all that sort of stuff, which I will, I will do. It's just now how will I do this with a baby as well. (participant #6)

- Sub-theme: Support required to maintain lifestyle changes

Some, but not all women were interested in receiving support around diet and exercise post-partum. More women expressed interest in support in a face-to-face setting rather than via email. Some preferred group settings and others felt more comfortable with individual settings.

“talking to other mothers who have children; um, you know, finding other strategies of you know, what they’re doing, how… how it’s worked for them, how it hasn’t worked for them” (participant #1)

“I think maybe diabetes wise, like I know I'm gestational, and I most likely may not have it after. But I think maybe ways to stop that from being something more permanent.” (participant #11)

“I think um especially exercising after you've had a baby, like knowing what you can do would be really beneficial for new mums, and making sure like little changes of interacting with your baby while you're making those healthy choices and stuff like that. Because you don't always know what you can and can't do physically after you've had the baby.” (participant #12)

Discussion

In this mixed-methods study evaluating pregnant women's experiences of The Healthy Lifestyle in Pregnancy Project (HiPP), we identified patient perspective barriers and enablers for the implementation of an integrated healthy lifestyle intervention embedded in routine antenatal care for women with obesity. Overall, women have good risk perception and are motivated to make healthy lifestyle changes, but initially lack sufficient skills to implement them. Qualitative data identified themes of: service support enabled change; drivers of motivation to behaviour change; social support; barriers to making change and post-partum lifestyle and needs. On triangulation of data, qualitative and quantitative findings aligned. These learnings provide insight into important factors for improving the implementation model.

In early pregnancy, 70% of women reported gaining weight in the year prior. This is comparable to an Australian study of women in preconception, showing 54% had weight gain in the previous 12 months (38). Here, the vast majority (80%) had attempted to lose weight, but had done so independently, with only 32% consulting a health professional. This concurs with findings from another preconception study, where few women had health checks prior to pregnancy to optimise their health and/or for weight management advice (39). Generally, women had reasonable risk perception, and were able to recognise the target weight gain and risks related to excess weight gain, consistent with existing literature (40). This may be partly explained by good background education levels and because women had completed their first midwife appointment (and possibly their first intervention session), where they would have received basic lifestyle information.

Of interest, women entered pregnancy with high expectations, all (100%) believed that they could manage healthy lifestyles and weight in pregnancy and almost all (97%) intended to take actions to prevent excess weight gain. However, when directly questioned about their confidence regarding eating and physical activity, confidence was lower at 74% and 67% respectively. This may be related to the style of question, with scaled question format more

likely to reflect the person's true feelings. Self-management strategy questions highlighted that women have good intentions for behaviour change but find implementation and relapse management difficult. This highlights that practising behaviour change is key to improving self-management and confidence, whilst reducing barriers. Additionally, women were more likely to be motivated to change and to keep track of their diet (55%) than exercise (41%). As both diet and exercise interventions offer benefits in pregnancy (9), interventions should aim to support enhancing both components.

Later in pregnancy, women reported strong satisfaction with the service provided, with 88% reporting satisfaction with information provided about lifestyle and 90% describing a good relationship with their healthcare provider. The reported satisfaction is higher than that reported in Australia in routine antenatal care (17). This strong satisfaction may have contributed to improved self-management and improvement in diet (making time to prepare healthy meals, having food available for quick healthy meals, more likely to try new foods and recipes, and replacing snack foods with healthier alternatives). Additionally, women weighed themselves more regularly over the course of the intervention. Self-weighing has previously been shown to enhance intervention efficacy in the context of intervention support, but not in control groups without lifestyle support (41-43).

Quantitative data showed that women have healthy lifestyle intentions, but in some cases lack sufficient skills and confidence to implement them, emphasising that pregnancy is a 'teachable moment' (8). Qualitative analysis explored how and why behaviour change was or was not made, and the strengths and weaknesses of the intervention. Key themes identified that the service clearly enabled change, with strong rapport between intervention staff and women. This confirms the overall high satisfaction women had with the service, with the majority of women having a good relationship with their health professional. Continuity of care with the same intervention staff promoted relationship building and trust, as described in other studies (26). This social support is an important technique effective in lifestyle pregnancy interventions (44, 45). Influence of family was an important theme in behaviour change, with a stronger

support system facilitating positive change, with demonstrated reach to other close family members also shown. With women previously reported to be the main influencers of family lifestyle behaviours (46), this has significant public health implications, with potential for wider beneficial effects beyond individual improvements to health behaviours.

Exploratory studies have indicated that women desire clear, unambiguous and personalised strategies (13, 17, 18, 47, 48) for making lifestyle changes in pregnancy. Confidence is considered a key element for behaviour change during pregnancy according to the Theory of Planned behaviour (34, 49). The challenging factor is how to enhance confidence and motivation to implement behaviour change. Here, women report that intervention staff largely provide this support, enabling success and a sense of achievement and improved confidence. When women saw they had healthy weight gain, this positively impacted their self-esteem, as previously described (50). Women noted that dietary changes were easier to sustain as the pregnancy progressed, compared with physical activity, across both quantitative and qualitative data highlighting the need for effective, supportive strategies to target realistic and achievable physical activity goals. Quantitative analysis demonstrated improved self management behaviours and in the qualitative component, a key theme was that the clinic enabled behaviour change, identifying triangulation of findings here.

Women identified a number of motivators for behaviour change, either intrinsic, due to concern regarding their baby's well-being, or extrinsic such as being accountable to health professionals, reflecting international research (18, 26, 40, 51, 52). Women also identified barriers to making change. Intrinsic (fatigue, medical problems, self-control) and extrinsic (time, inclement weather, work, other children and finances) barriers are universally recognised in this field, as women are challenged to balance everyday demands. Here, the interviews expanded insights of barriers gleaned from quantitative analysis. In contrast to many qualitative studies of health professionals' experiences that describe reticence discussing obesity/gestational weight gain for fear of upsetting women (13-15), here very few

women identified talking about their weight as a sensitive issue, and this may be due to intervention staff expertise in this area. Reflecting on the relationship between healthcare providers and women, some described feeling judged in the initial stages, consistent with other studies (18). Some women speculated this may be related to stigma around their weight and feeling vulnerable to negative attitudes that have been described previously (18, 26). These feelings were expressed in the interview and not in the questionnaires, highlighting the benefit of qualitative analysis. Women wish to feel understood and treated with respect (53) and this feedback can expand learnings and be applied to improve the healthcare provider and recipient relationships.

There was variation in the anticipated sustainability of post-partum lifestyle changes between women with and without other children. Women without children were less confident in their ability to find time to exercise. Some women wanted postnatal support in varying formats. Engaging women postpartum is difficult and these factors need to be incorporated into future implementation models. Evidence is emerging that engagement in pregnancy and continuation post-partum is more successful than isolated post-partum approaches. With health benefits for mother and child demonstrated with healthy lifestyle in preconception, pregnancy and post-partum, a continuum approach would be ideal to support women at this high-risk period (54, 55).

Overall, this study demonstrates that women are gaining weight preconception and appear very motivated at the commencement of pregnancy to improve lifestyle, but lack of confidence hampers their success. Women want uncomplicated, clear advice. This intervention is designed to implement small, achievable changes that keep expectations realistic and remove the overwhelming feeling of having to change everything at once, by focussing on what is important to the woman at the time. Practising these techniques enhances self-management, problem solving and self-efficacy and changes are associated with weight gain prevention which in turn improves confidence in women. Facilitating factors are social support and rapport

with intervention staff. Pregnancy is a time where increased support is needed by women and this intervention assisted in promoting this both within and outside of the intervention which is likely to be another factor associated with its success.

Strengths and limitations

A strength of this research is the mixed-methods design, evaluating a pragmatic lifestyle intervention delivered embedded in routine maternity care, reflecting real world settings. By using quantitative and qualitative methods, we enriched our understanding of women's experiences. In most aspects, results were strongly aligned, with coherence of quantitative and qualitative findings, with more in-depth insights from the thematic analysis. Additionally, the study included women from a low SES, diverse ethnic background catchment, increasing generalisability. The findings complement those of our health professionals' perspectives (12). Together, the studies have a role in informing implementation and scale of evidence-based, cost-effective antenatal lifestyle interventions. Possible limitations include the researcher's prior clinical experience in the service that may have influenced interpretation of the participant's response, however thematic analysis was completed by two independent researchers. Additionally, this experience is of a single clinical service in a larger health setting and will need to be generalised.

Conclusions

Overall, healthy lifestyle was a high priority for pregnant women with obesity. Positive pregnancy care and lifestyle intervention experiences were reported, including satisfaction and being well-supported and involved. Prior to the intervention, women were able to identify strategies they could use to manage their lifestyle, but had less confidence to implement these changes, with confidence bolstered by the intervention. Ultimately, embedding an effective lifestyle intervention into routine care with dedicated trained health professionals enabled women to feel confident and empowered to make changes. Women identified weaknesses and strengths in their pregnancy care experiences and suggested ideas for improved service

provision. Combining these findings with health professional perspectives will inform the scale-up of effective guideline recommended interventions in pregnancy more broadly.

List of abbreviations

BMI: Body mass index

GDM: Gestational Diabetes Mellitus

GWG: Gestational Weight Gain

HiPP: Healthy Lifestyle in Pregnancy Project

IOM: Institute of Medicine

RCT: Randomised controlled trial

Declarations

Ethics approval and consent to participate

The study was approved by Monash Health and Monash University ethics committees and registered with the Australian New Zealand Clinical Trials Registry (no.12620000985987).

Verbal consent was obtained from participants prior to the interview, after reading a participant information sheet. Written informed consent was obtained from all participants prior to the interview.

Consent for publication

Not applicable

Availability of data and Materials

Requests for de-identified data may be requested by written application to the corresponding author and will be considered on an individual basis.

Competing interests

The authors declare they have no competing interests

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Author's contributions

The research design was developed by RG, HT, JB and CH. RG recruited participants and conducted interviews. RG analysed the quantitative data, and RG and CL analysed the qualitative data, cross-checking results and identifying themes. RG drafted the manuscript. Feedback was provided by all authors. All authors read and approved the final manuscript.

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Additional File 1

Questionnaire 1

PART 1

The following questions help us understand the women attending our services.

Please mark ONE response only to questions 1-5. There are no right or wrong answers.

1. **Do you believe your feedback about Dandenong Women's Antenatal Services can help improve the Service?**
   - ☐ Yes, definitely
   - ☐ Yes, moderately
   - ☐ Somewhat
   - ☐ No, not much
   - ☐ No, not at all

2. **We sent some pamphlets about pregnancy to you in the mail with your booking appointment. Were these pamphlets helpful?**
   - ☐ Yes, extremely
   - ☐ Yes, very
   - ☐ Somewhat
   - ☐ No, not much
   - ☐ No, not at all

3. **What is the highest level of schooling you have completed? (mark the highest grade)**
   - ☐ Year 10 or equivalent
   - ☐ Year 11 or equivalent
   - ☐ Year 12 or equivalent
   - ☐ Post school certificate/ diploma
   - ☐ Bachelor degree and above

4. **Do you currently work?**
   - ☐ Full time
   - ☐ Part time / casual
   - ☐ No paid work

5. **What is your average yearly income (before tax) that your household receives each year, including any financial support (eg. fortnightly benefits)?**
   Household= salary of all income earners including yourself, partner and others

   ☐ $ 40,000 or less
   ☐ $41,000-64,000
   ☐ $65,000- 80,000
   ☐ more than $81,000

6. **Have you been diagnosed, or told by your doctor that you have any of the following? (cross all that apply)**

   ☐ Diabetes in pregnancy
   ☐ Type 1 diabetes
   ☐ Type 2 diabetes
   ☐ Heart disease
   ☐ High blood pressure
   ☐ Asthma
   ☐ Depression
   ☐ Cancer
   ☐ Polycystic ovarian syndrome (PCOS)
   ☐ Osteoarthritis
   ☐ I don't have any of these conditions

PART 2

1. **How often are you currently weighing yourself?**
   ☐ Daily ☐ Weekly ☐ Monthly ☐ Occasionally ☐ Never

2. **Have you gained weight in the past year (before you were pregnant)?**
   ☐ Yes ☐ No ☐ Unsure

3. **If yes, how much have you gained?**
   ☐ 1-2kg
   ☐ 3-4kg
   ☐ 5 kg
   ☐ 6-10kg
   ☐ greater than 10 kg

4. **Have you attempted to lose weight in the last 12 months?**
   ☐ Yes ☐ No

5. **In the past 12 months have you consulted a professional to help you manage your weight?**
   ☐ Yes ☐ No

If yes, who have you seen?

- ☐ Doctor
- ☐ Dietician
- ☐ Natural therapist
- ☐ Personal trainer
- ☐ Life coach
- ☐ Other (please describe_____

6. In the past 12 months in order to help you have a healthy lifestyle, have you…? (cross all that apply)

- ☐ Increased vigorous exercise (eg. running, cycling)
- ☐ Cut down size of meal
- ☐ Cut down on snack foods and takeaway/ fats and sugar
- ☐ Vomited
- ☐ Skipped meals
- ☐ Increased smoking
- ☐ Attended a weight loss program (eg. Weight Watchers or Jenny Craig)
- ☐ Used meal replacement shakes or bars
- ☐ Had surgery (eg. gastric banding)
- ☐ Attended an structured exercise program (eg. personal trainer)
- ☐ Other (please describe) _____
- ☐ I have not made any changes

7. Before you were pregnant, how satisfied did you feel with

	Very dissatisfied	A little dissatisfied	Somewhat dissatisfied	Quite satisfied	Very satisfied
a. Your weight?	☐	☐	☐	☐	☐
b. Your body shape?	☐	☐	☐	☐	☐

PART 3

1. How much weight gain during your pregnancy do you believe is best for your health and the health of your baby? (please select one only)

- ☐ No weight gain
- ☐ 0-5 kg
- ☐ 5-9 kg
- ☐ 9-15kg
- ☐ 15-20 kg
- ☐ 20kg or above

2. **I believe that increased weight gain in pregnancy is associated with: (please select all that apply)**
   - ☐ More nutrients for the baby
   - ☐ Big babies (macrosomia)
   - ☐ Early delivery (preterm labour)
   - ☐ Need for induction of labour
   - ☐ Diabetes in pregnancy (gestational diabetes)
   - ☐ High blood pressure in pregnancy
   - ☐ Baby kicking more
   - ☐ Baby not feeding well after delivery
   - ☐ Mother developing diabetes in the future
   - ☐ Your child becoming overweight as a child or an adult
   - ☐ Baby developing asthma
   - ☐ None of the above

Please answer the following statements according to how you were thinking when you <u>first became aware that you were pregnant</u>

1. **I think it is important to have a healthy lifestyle during pregnancy**

Strongly agree	Agree	Somewhat agree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

2. **I thought I was at risk of gaining too much weight in pregnancy**

Strongly agree	Agree	Somewhat agree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

3. **I believe I can manage to have a healthy lifestyle and healthy weight gain in pregnancy**

Strongly agree	Agree	Somewhat agree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

4. **I plan to take action to prevent too much weight gain**

Strongly agree	Agree	Somewhat agree	Disagree	Strongly disagree
☐	☐	☐	☐	☐

PART 4

Complete every question by drawing a circle around the number that describes how you feel.

1. **How <u>important</u> is it to you to make healthy lifestyle changes during your pregnancy regarding your eating?**

Not at all ---------- Completely

1 2 3 4 5 6 7 8 9 10

2. **How <u>important</u> is it to make healthy lifestyle changes during your pregnancy regarding your physical activity?**

Not at all ---------- Completely

1 2 3 4 5 6 7 8 9 10

3. **How <u>ready</u> are you to make healthy lifestyle changes during your pregnancy regarding your eating?**

Not at all ---------- Completely

1 2 3 4 5 6 7 8 9 10

4. **How <u>ready</u> are you to make healthy lifestyle changes during your pregnancy regarding your physical activity?**

Not at all ---------- Completely

1 2 3 4 5 6 7 8 9 10

5. **How <u>confident</u> are you to make healthy lifestyle changes during your pregnancy regarding your eating?**

Not at all ---------- Completely

1 2 3 4 5 6 7 8 9 10

6. **How <u>confident</u> are you to make healthy lifestyle changes during your pregnancy regarding your physical activity?**

Not at all ---------- Completely

1 2 3 4 5 6 7 8 9 10

PART 5

We are interested in your feelings over the last 12 months.

Complete every question by crossing one box like this: [x]

	Never	Occasionally	Often	Very often	Always
1. I think about the benefits I will get from being physically active	□	□	□	□	□
2. I try to think more about the benefits of physical activity and less the hassles of being active	□	□	□	□	□
3. I make backup plans to be sure I get enough physical activity	□	□	□	□	□
4. When I get off track with my physical activity I find ways to get back on track	□	□	□	□	□
5. I ask friends and family to walk with me to help me stay active	□	□	□	□	□
6. I can stick to my plans to be active each week	□	□	□	□	□
7. When I set goals I choose activities that I enjoy	□	□	□	□	□
8. I know when I should do more activity	□	□	□	□	□
9. I plan ahead of time to be active	□	□	□	□	□
10. I look for information about nutrition and healthy eating from books, magazine, internet etc	□	□	□	□	□
11. I read articles about the benefits of being active from magazines, books or the internet	□	□	□	□	□
12. I seek information about my weight from my GP	□	□	□	□	□

13. I keep track of how much physical activity I do each week	□	□	□	□	□
14. I do things to make walking or other activity more enjoyable	□	□	□	□	□
15. I watch my weight	□	□	□	□	□
16. I watch what I eat	□	□	□	□	□
17. I keep track of what I eat and know how much I should eat	□	□	□	□	□
18. I can stop myself overeating	□	□	□	□	□
19. I say positive things to myself about eating healthy food	□	□	□	□	□
20. If I don't eat healthy food I think about ways to do better next time	□	□	□	□	□
21. I make plans to change my diet/ drinking habits	□	□	□	□	□
22. **I weigh myself regularly**	□	□	□	□	□
23. I read labels to help me choose healthy food	□	□	□	□	□
24. I make sure I have time to prepare healthy meals	□	□	□	□	□
25. I have food available for quick healthy meals	□	□	□	□	□
26. I try new foods and recipes to make healthy food enjoyable	□	□	□	□	□
27. **I eat healthy food**	□	□	□	□	□
28. I replace snack foods with healthier alternatives	□	□	□	□	□
29. I decide what to eat at the last minute	□	□	□	□	□

Thank you very much for completing the questionnaire. We appreciate your time.

Please take a moment to check and see that you have completed all the questions.

Additional File 2

Questionnaire 2

PART 1

Please mark ONE response to each of these questions. There are no right or wrong answers.

1. **During your pregnancy care, how satisfied were you with the information that you obtained about a healthy lifestyle (including dietary changes and exercise)?**

☐ Very satisfied

☐ Satisfied

☐ Neither satisfied nor dissatisfied

☐ Dissatisfied

☐ Very dissatisfied

☐ This information was not mentioned

2. **Has your antenatal care team been helpful in assisting and supporting you to be more physically active?**

☐ Yes, extremely

☐ Yes, very

☐ Somewhat

☐ No, not much

☐ No, not at all

3. **Has your antenatal care team been helpful in assisting and supporting you to have healthy eating?**

☐ Yes, extremely

☐ Yes, very

☐ Somewhat

☐ No, not much

☐ No, not at all

4. **Did you feel you had a good relationship with your health professional team?**

☐ Yes, extremely

☐ Yes, very

☐ Somewhat

☐ No, not much

☐ No, not at all

5. Were you given enough time to ask questions and discuss your pregnancy health during your appointments?

☐ Yes, definitely

☐ Yes, very

☐ Somewhat

☐ No, not much

☐ No, not at all

6. Did you feel involved in decision making about your pregnancy care?

☐ Yes, definitely

☐ Yes, very

☐ Somewhat

☐ No, not much

☐ No, not at all

PART 2

1. **I took definite actions during my pregnancy to have a healthy lifestyle and reduce my risk of gaining too much weight**

☐ Yes, definitely

☐ Yes, mostly

☐ Somewhat

☐ No, not much

☐ No, not at all

<u>If you answered 'yes', please complete Q 2 to 5. If you answered 'no' please go to question 6.</u>

2. What would you consider to be the main changes you made?

(Please mark all the ones that apply)

☐ I eat more fruit and vegetables

☐ I drink more water

☐ I eat more low fat dairy products (e.g. milk, cheese and yoghurt)

☐ I have less fruit juice, cordial and soft drink

☐ I have less snack foods (e.g. chocolate, chips etc)

☐ I have less takeaway and convenience foods

☐ I have increased the number of times I exercise each week

☐ I have increased the time I spend on each exercise session

☐ I have increased the physical intensity of exercise sessions

☐ I make more time for relaxation

☐ Other _____

3. **I have worked on maintaining the lifestyle changes I have made to my diet**

☐ Yes, definitely

☐ Yes, very

☐ Somewhat

☐ No, not much

☐ No, not at all

4. **I have worked on maintaining the lifestyle changes I have made to my physical activity**

☐ Yes, definitely

☐ Yes, very

☐ Somewhat

☐ No, not much

☐ No, not at all

5. How confident are you that you can maintain any lifestyle changes that you have made after you deliver your baby?

☐ Very confident

☐ Confident

☐ Partly confident

☐ A little confident

☐ Not confident at all

6. What would you consider to be the main barriers to making any lifestyle changes to your diet and physical activity?

☐ Lack of time

☐ Fatigue/tiredness

☐ Taking care of other children

☐ Family/spousal influences

☐ Change in circumstance (i.e. moving house, going overseas)

☐ Change in work situation

☐ Illness (yourself or another family member)

☐ Too much effort

☐ No motivation/ feeling lazy

☐ Not confident in making changes

☐ Lack of support from family/friends

☐ Bad weather

☐ Not important to me

☐ Other _____

7. How often are you currently weighing yourself?

☐ Daily ☐ Weekly ☐ Monthly ☐ Occasionally ☐ Never

PART 3

We are interested in your feelings during this pregnancy.

Complete every question by crossing one box like this: [x]

	Never	Occasionally	Often	Very often	Always
1. I think about the benefits I will get from being physically active	□	□	□	□	□
2. I try to think more about the benefits of physical activity and less the hassles of being active	□	□	□	□	□
3. I make backup plans to be sure I get enough physical activity	□	□	□	□	□
4. When I get off track with my physical activity I find ways to get back on track	□	□	□	□	□
5. I ask friends and family to walk with me to help me stay active	□	□	□	□	□
6. I can stick to my plans to be active each week	□	□	□	□	□
7. When I set goals I choose activities that I enjoy	□	□	□	□	□
8. I know when I should do more activity	□	□	□	□	□
9. I plan ahead of time to be active	□	□	□	□	□
10. I look for information about nutrition and healthy eating from books, magazine, internet etc	□	□	□	□	□
11. I read articles about the benefits of being active from magazines, books or the internet	□	□	□	□	□
12. I seek information about my weight from my GP	□	□	□	□	□

13. I keep track of how much physical activity I do each week	□	□	□	□	□
14. I do things to make walking or other activity more enjoyable	□	□	□	□	□
15. I watch my weight	□	□	□	□	□
16. I watch what I eat	□	□	□	□	□
17. I keep track of what I eat and know how much I should eat	□	□	□	□	□
18. I can stop myself overeating	□	□	□	□	□
19. I say positive things to myself about eating healthy food	□	□	□	□	□
20. If I don't eat healthy food I think about ways to do better next time	□	□	□	□	□
21. I make plans to change my diet/ drinking habits	□	□	□	□	□
22. **I weigh myself regularly**	□	□	□	□	□
23. I read labels to help me choose healthy food	□	□	□	□	□
24. I make sure I have time to prepare healthy meals	□	□	□	□	□
25. I have food available for quick healthy meals	□	□	□	□	□
26. I try new foods and recipes to make healthy food enjoyable	□	□	□	□	□
27. **I eat healthy food**	□	□	□	□	□
28. I replace snack foods with healthier alternatives	□	□	□	□	□
29. I decide what to eat at the last minute	□	□	□	□	□

Thank you very much for completing the questionnaire. We appreciate your time.

Please take a moment to check and see that you have completed all the questions.

Additional file 3

Interview schedule for participants

- **Explore maternity service engagement**

We would like to get your opinion on what you liked/disliked about attending the maternity clinic, in particular your experience with the health coach and endocrinologist.

1. What was positive?

Prompt: Did you feel the aims of the clinic were explained to you?
What was your relationship like with the obstetrician/midwife/endocrinologist/health coach?
How were you involved in decision making?
Did you feel like you had the opportunity to ask questions?

2. What was negative?

Prompt: Was the time of the clinic (afternoon) an issue?
We know you may have been seeing lots of people on the one day, was waiting time an issue?

- **Behaviour change**

1. What advice were you given about having a healthy pregnancy?
   Prompt: Tell me about the advice the health coach/obstetrician/endo/midwife gave you?
   What advice were you given about diet/food/exercise/weighing yourself?
2. What did you feel were the main goals of the lifestyle sessions?
3. What did you find most beneficial?
4. Was the level of support provided adequate to enable you to achieve a healthier lifestyle in pregnancy?
5. Following the sessions were you ready to change?
6. If you did make any changes, can you tell me what they were?
7. What helped you make these changes?
   Prompt: setting your own goals/ weighing yourself/ practical advice eg. food substitution/ knowing you were coming back for each review/ breaking down larger changes into smaller sustainable changes
8. Thinking about the changes you made, did it make you feel more confident in yourself?
9. Some women found it difficult to make changes. Were there any barriers that prevented you from fulfilling lifestyle goals?
   Prompt: Family responsibilities/work responsibilities (too busy)/ cost (too expensive)/easier to wait until the pregnancy is complete and then starting afresh with lifestyle changes
10. Can you think of anything else the maternity clinic could have provided differently to make this easier for you?

11. If you have made changes, have you found your family/friends are supportive? In what way?

12. Have your changes had any impact on your family and friends?
    Prompt: Are you buying/cooking different food?
    Are you exercising as a family?

13. Tell me about anything you found challenging or difficult in the clinic
    Prompt: Talking about your weight or eating habits
    Can you describe this experience? Was it supportive?

14. Thinking about the changes you have made, do you feel they are sustainable to you? (eg. can you continue any of these changes after your baby is born?) Which ones do you think you are most likely to keep up?
    Prompt: Diet/exercise/weighing/sleep

15. Is there any support you would like to receive in the first 6 months after having a baby?
    Prompt: about staying healthy, eating well and exercising?
    Would you prefer to receive this to be face-to-face (appointment) or written (mail/email)?
    If face-to-face, would you prefer this individually or in a group session with other new mums? (ie. part of maternal child health experience)

Is there anything more you would like to add?

Demographic questions (only for women who have not completed questionnaire 1)

What is the highest level of schooling you have completed? (mark the highest grade)

- ☐ Year 10 or equivalent
- ☐ Year 11 or equivalent
- ☐ Year 12 or equivalent
- ☐ Post school certificate/ diploma
- ☐ Bachelor degree and above

Do you currently work?

- ☐ Full time
- ☐ Part time / casual
- ☐ No paid work

What is your average yearly income (before tax) that your household receives each year, including any financial support (eg. fortnightly benefits)?

Household= salary of all income earners including yourself, partner and others

- ☐ $ 40,000 or less
- ☐ $41,000-64,000
- ☐ $65,000- 80,000
- ☐ more than $81,000

Have you been diagnosed, or told by your doctor that you have any of the following? (cross all that apply)

- ☐ Diabetes in pregnancy
- ☐ Type 1 diabetes
- ☐ Type 2 diabetes
- ☐ Heart disease
- ☐ High blood pressure
- ☐ Asthma
- ☐ Depression
- ☐ Cancer
- ☐ Polycystic ovarian syndrome (PCOS)
- ☐ Osteoarthritis
- ☐ I don’t have any of these conditions

Chapter 4. Risk perceptions, health beliefs and satisfaction with diagnosis in women with gestational diabetes (GDM)

4.1 Introduction

One of the themes of my PhD is to evaluate experiences of high-risk women attending antenatal services, as well as health professionals' perspectives. In the previous chapter, I analysed the experiences of women with obesity. In this chapter, I focus on another group of high-risk women, women who develop gestational diabetes. Including the perspective of women with this common pregnancy complication enhances our understanding of patient experience and will inform the implementation of strategies to achieve healthy pregnancy in high-risk women.

Gestational diabetes (GDM) is a lifestyle and obesity related condition defined as glucose intolerance with onset or first recognition during pregnancy. Its prevalence varies from 4.6-25% depending on the diagnostic criteria and the population studied (34, 35). Increased risk of GDM is associated with maternal age over 35 years, increasing body weight, ethnicity or a family history of type II diabetes (T2DM). The diagnosis carries significant short-term and long-term risk of morbidity for mother and child (36). Treatment of GDM has been found to decrease perinatal morbidity, macrosomia and may also improve the woman's health-related quality of life (37).

Women with overweight and obesity are more likely to develop GDM than women with normal weight (38), and adverse lifestyle plays a significant role here. As the prevalence of obesity in reproductive aged women rises, the incidence of GDM rises as well (39). Preconception care and early pregnancy care can reduce preventable diabetes and obesity-related complications in high-risk women. A large part of treatment for GDM involves addressing adverse lifestyle factors, with realistic goal setting, health lifestyle and diabetes self-management skills (40). This requires expertise from a multidisciplinary team, involving obstetricians, midwives, endocrinologists, diabetes nurse educators, dieticians, exercise physiologists and health coaches. In a similar vein to managing obesity and gestational weight gain in pregnancy, management of diabetes in pregnancy involves individualised lifestyle and pharmacological management (41). Maintaining engagement and motivation of these women during pregnancy is vital for success.

In 2014, there was discussion worldwide regarding changing the criteria for GDM. With the adoption of new International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria (35), it was estimated there would be an increase of up to 50% in the number of women diagnosed (42). This increase in diagnosis with more liberal criteria was postulated to have significant potential implications including service burden, healthcare cost and impact of diagnosis and treatment of GDM. At this time, there was limited research in these areas. As services expanded to respond to the increasing incidence of GDM, we considered it important to investigate whether services were currently meeting patients' needs and where any gaps may be.

At this stage, there was little current data on the impact of diagnosis in multicultural diverse populations, with ready access to free health services and where new criteria were being considered, as was the situation at Monash Health, Victoria. In this chapter, my aim was to investigate satisfaction with diagnosis, risk perception and health beliefs to improve understanding of barriers and enablers of lifestyle change to inform optimisation of treatment of GDM.

Women attending GDM clinic completed a questionnaire during their pregnancy. I sought to understand satisfaction with information provision at diagnosis, risk perceptions related to maternal and neonatal health outcomes, and confidence in GDM treatment. Women were largely positive about their experience of GDM diagnosis. Most understood the potential benefit of lifestyle changes and insulin use. Risk perception for further GDM and T2DM was reasonable. We identified that explanation of screening tests and provision of information could be improved.

These findings highlighted that future clinical practice should focus on improving education about the long-term complications of GDM. We also understood the limitations of quantitative studies in demonstrating the depth of data related to experiences of treatment during pregnancy, and that qualitative research would add to this description.

There is commonality in the provision of medical care for women with GDM and for women with obesity during pregnancy, as they are both high-risk populations with similar needs. The lessons learnt from one service can be easily and effectively adapted for another. With this in mind, when planning my evaluation of patient experience in chapter three, I was able to use these findings around risk perception and health beliefs to inform the planning of questionnaires and the qualitative component.

4.2 Satisfaction with diagnosis process for gestational diabetes mellitus and risk perception among Australian women

Rebecca F Goldstein, Melanie E Gibson-Helm, Jacqueline A Boyle, Helena J Teede

Satisfaction with diagnosis process for gestational diabetes mellitus and risk perception among Australian women

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CLINICAL ARTICLE

Satisfaction with diagnosis process for gestational diabetes mellitus and risk perception among Australian women

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ABSTRACT

Objective: To evaluate satisfaction with diagnosis, risk perceptions, and health beliefs among women with gestational diabetes mellitus (GDM). *Methods:* In a cross-sectional questionnaire-based study, participants with GDM diagnosed after 26 weeks of pregnancy were recruited from hospital-based services at Monash Health (Melbourne, VIC, Australia) and through newspaper advertisements between 2008 and 2010. Eligible participants—aged at least 18 years and able to read English—completed a questionnaire. *Results:* Among 46 women who completed the questionnaire, 38 (83%) were satisfied with the explanation of the GDM screening test and 31 (67%) felt that the results were explained well. Generally, women were satisfied with the information provided about lifestyle management (29 [81%] of 36) and medical therapy (26 [72%] of 36). Most women (41 [89%]) associated poor GDM control with perinatal complications. Additionally, many participants thought that insulin (35 [76%]) and lifestyle changes (30 [65%]) could reduce macrosomia. A total of 37 (82%) of 45 women perceived that they were at risk of future GDM, and 33 (73%) thought they had an increased risk of type 2 diabetes. Most women believed that they could change these risks (29 [64%] and 37 [82%] of 45, respectively). *Conclusion:* Women were largely positive about their experience of GDM diagnosis. Explanation of the screening test and provision of information could be improved. Risk perception was reasonable.

1. Introduction

Gestational diabetes mellitus (GDM) is defined as glucose intolerance with onset or first recognition during pregnancy [1]. Its prevalence varies from 4.6% to 25% depending on the diagnostic criteria used and the study population [2–4]. Increased risk of GDM is associated with a maternal age of 35 years or older, higher body weight, some ethnic origins, and a family history of type 2 diabetes (T2DM). Diagnosis of GDM carries a significant short-term and long-term risk of morbidity for mother and child [5]. Treatment of GDM decreases perinatal morbidity and macrosomia, and can improve the woman's health-related quality of life [6].

The greatest clinical focus has been on diagnosis of GDM, for which screening and clinical intervention are routinely available in Australia. However, controversy surrounds the diagnostic criteria for GDM. In 1999, WHO guidelines were developed to identify women who are at risk of developing type 2 diabetes later in life (fasting plasma glucose ≥7 mmol/L, 2-hour plasma glucose ≥7.8 mmol/L) [7]. More recent guidelines base their recommendations on pregnancy outcomes, have a lower fasting glycemic threshold (≥5.1 mmol/L), and an additional 1-hour glucose level for diagnosis (≥10.1 mmol/L) [3]. If these new guidelines are globally adopted, the number of diagnoses would increase by approximately 50% [8]. This increase could have significant implications for service burden and healthcare costs, and might affect the diagnosis and treatment of GDM. To date, there is limited research in these areas [9], and it is important both to investigate whether current services are meeting patients' needs and to identify where any gaps might be.

Most research on the impact of diagnosis is restricted to studies performed before universal screening [10,11], those focusing on ethnic minorities or the postpartum period [12,13], or those in countries with no universal health care [14]. As a result, the aim of the present study was to investigate satisfaction with diagnosis of GDM, risk perception, and health beliefs among a multicultural population with access to free health care to improve understanding of barriers and enablers of lifestyle change and to inform optimization of the treatment of GDM once diagnosed.

2. Materials and methods

The present cross-sectional, questionnaire-based study was conducted between June 1, 2008, and July 31, 2010. Women were recruited from hospital-based GDM clinics at Monash Health, Melbourne, VIC,

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0020-7292/

Australia, and through newspaper advertisements. Eligible participants were aged at least 18 years, were able to read English, were pregnant and had a diagnosis of GDM after 26 weeks, and did not have pre-existing diabetes. The present study was a subset of a larger study that investigated health-related behaviors among women with lifestyle-related diseases, which was approved by Monash Health Human Research Ethics Committee A (project no.07070C). All participants provided informed consent before the study began.

During the study period, GDM was diagnosed according to Australian diagnostic criteria via a two-step process of a 50-g glucose challenge test, followed by a 75-g glucose tolerance test. GDM clinical staff members were not engaged in the study or aware of the study's aims. Standard care included a group information session with a diabetes nurse educator and a dietician, provision of written information, and an individual endocrinology review with follow-up as needed on a weekly-to-monthly basis.

The questionnaire devised for the study could be completed online or on paper. It contained questions regarding demographic characteristics, satisfaction with information provision at diagnosis, risk perceptions related to neonatal and maternal health outcomes, and confidence in GDM treatment. The questions included: "How satisfied were you with the information that was given to you about GDM at the time of diagnosis?" with responses on a 5-point Likert scale (very satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied, and very dissatisfied); "Which of the following are you aware can occur if GDM is not controlled?" with multiple options provided; and "How confident are you that medical therapy will improve your GDM?" with responses on a 5-point Likert scale (from extremely confident to not at all confident). Responses on a Likert scale were grouped.

Statistical analysis was conducted by SPSS version 20 (IBM, Armonk, NY, USA). Categorical data are presented as number (percentage). Continuous data are presented as the median (interquartile range [IQR]).

3. Results

During the study period, the questionnaire was distributed to 115 eligible women. Overall, 58 (50%) women returned the questionnaire, and 46 (40%) had completed relevant sections and were included in analysis. Of these 46 women, 44 (96%) attended Monash Health, and 2 (4%) had responded to the newspaper advertisement and were treated at other clinics.

The median participant age was 33 years (IQR 26–40). Most participants had been born in Australia and almost one-third were in the first pregnancy (Table 1). Among the 30 women with a previous pregnancy, 11 (37%) had a history of GDM. Parity or GDM in a previous pregnancy did not affect the results (data not shown).

Among the 46 women who completed the questionnaire, 38 (83%) were satisfied with the explanation of the GDM screening test and 31 (67%) felt that the results of the screening test were explained well. Overall, 31 (69%) of 45 women recalled being provided with information at the time of diagnosis. Satisfaction with the information given about lifestyle management was reported by 29 (81%) of 36 women, and satisfaction with that given about medical therapy by 26 (72%) (Fig. 1). A total of 25 (69%) women were satisfied with the information provided about long-term complications. Women identified general practitioners (28 [68%] of 41), obstetricians (24 [59%] of 41), and midwives (20 [49%] of 41) as key sources of information.

Overall, 41 (89%) women understood that poor GDM control was associated with perinatal complications including macrosomia, whereas only 8 (17%) women perceived anxiety and depression to be complications of uncontrolled GDM (Fig. 2). Three-quarters (35 [76%]) thought that poor control was associated with induction of labor and/or cesarean delivery, and the same number felt that it was linked to neonatal ward admission, neonatal hypoglycemia, or jaundice.

Additionally, 35 (76%) participants thought that insulin could reduce macrosomia and 30 (65%) believed lifestyle changes would reduce macrosomia. However, only 14 (30%) thought that insulin could reduce induction of labor and/or cesarean delivery and only 15 (33%) believed lifestyle changes could make a difference. More than half (27 [60%] of 45) thought that their fetus had an increased risk of diabetes later in life.

When questioned about GDM risk perceptions, 28 (61%) women thought that weight contributes to the risk of GDM. Many (37 [82%] of 45) perceived themselves to be at increased risk of GDM in the future and 29 (64%) of 45 believed that they could change their risk. More specifically, 44 (96%) of 46 were confident that lifestyle changes could improve their current GDM and 39 (89%) of 44 believed medical therapy would make a difference.

When asked about their perceptions of T2DM risk, 30 (65%) thought that weight contributes to the risk of T2DM. Nearly three-quarters (33 [73%] of 45) perceived themselves to be at an increased risk of diabetes as they aged, and 37 (82%) of 45 thought that they could change their risk in the future. Most were confident that lifestyle changes could prevent longer-term diabetes (42 [93%] of 45), whereas three-quarters (32 [73%] of 44) thought that medical therapy could prevent longer-term diabetes. More than half (27 [60%] of 45) thought that big lifestyle changes effectively prevent diabetes.

Table 1
Demographic characteristics of women with GDM living in Australia (n = 46).

Characteristic	Value[a]
Age, y	33 (26–40)
Born overseas	21 (46)
Previous pregnancy[b]	30 (68)
Previous GDM diagnosis[c]	11 (37)
Education after high school[d]	
Certificate/diploma	18 (40)
Bachelor/graduate degree	14 (31)
Postgraduate degree	5 (11)
No formal education	8 (18)
Work status	
Full-time work	16 (35)
Part-time work	11 (24)
No paid work	19 (41)
Gross annual household income, AUS$	
<40 000	12 (26)
40 000–80 000	15 (33)
>80 000	12 (26)
Information not given	7 (15)

Abbreviation: GDM, gestational diabetes mellitus.
[a] Values are given as median (interquartile range) or number (percentage).
[b] n = 44.
[c] Percentage calculated with total number of women with a previous pregnancy as the denominator.
[d] n = 45.

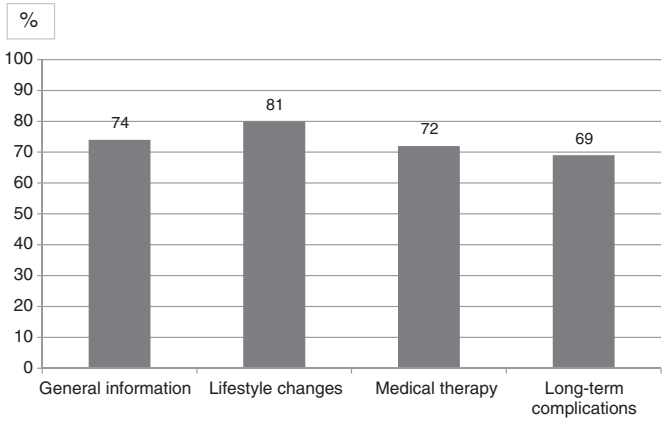

Fig. 1. Satisfaction with information provided at time of diagnosis of gestational diabetes mellitus.

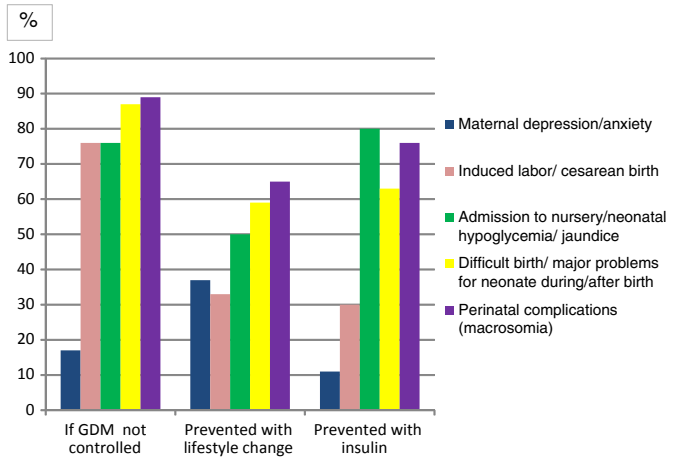

Fig. 2. Participants' understanding of the potential complications of gestational diabetes mellitus.

4. Discussion

The present study has assessed the impact of diagnosis among a sample of pregnant women with GDM within a multicultural population with access to free health care and universal GDM screening. Women were largely positive about their experience of GDM diagnosis. Provision of information regarding medical therapy and long-term complications were identified as areas for improvement. Encouragingly, most women associated maternal and neonatal complications with poor GDM control, and almost all had confidence that medical therapy and lifestyle change can prevent complications. Although most women identified themselves to be at risk for future GDM and T2DM, the impact of weight on risk of GDM and T2DM seemed to be underappreciated. Most participants understood the impact of lifestyle on reducing these risks.

Although most women were satisfied with the explanation of the screening test, approximately one-third reported that the results of the screening test were not explained adequately. Few studies have addressed women's experiences of GDM—in particular, satisfaction with diagnosis—but overall, the present findings are similar to previous Australian research on GDM test explanations [10]. The present study highlights an area for improved provision of care in the explanation of test results.

Notably, most women recalled being provided with information about GDM at the time of diagnosis. Most found the information regarding medical treatment, lifestyle changes, and long-term risk to be satisfactory, which is consistent with or better than research done in other countries [15,16]. To our knowledge, there are no quantitative data assessing satisfaction with GDM information and the present study contributes to this area. Future clinical practice should focus on improving education about the long-term complications of GDM.

Overall, women had a good understanding of the maternal and neonatal complications of GDM (in particular, macrosomia and assisted birth) and prevention of these complications. In general, women reported that both insulin and lifestyle can prevent complications, but noted insulin as more likely to prevent complications. When asked about their personal management of GDM, the women reported being slightly more confident about the efficacy of lifestyle than about medical therapy. To our knowledge, no other quantitative studies have addressed patients' understanding of management of GDM, which is essential knowledge before implementation of treatment.

In the present study of a multidisciplinary approach to managing GDM, most women perceived the risk of future GDM and T2DM. This finding is consistent with other studies, which have shown that 67% of women perceive a future risk when surveyed at delivery [17] and 82% when surveyed 3–5 years after diagnosis [15]. In contrast, in a postpartum study, Kim et al. [18] demonstrated that only 16% of women perceived an increased risk of T2DM despite recognizing a strong association between GDM and postpartum diabetes.

In the present study, a greater proportion of women felt that lifestyle changes would prevent diabetes as compared with medical treatment. We anticipate that these women might be responsive to lifestyle intervention programs, and there is evidence that lifestyle prevention programs have a role in preventing T2DM [19]. However, some studies among women with a history of GDM have shown that concern does not always translate into changing behavior [13,15,20]. The present study highlights the need to develop effective education methods to translate knowledge of lifestyle change into everyday practice.

The present study might be limited by selection bias. The women who volunteered could differ from the general population of women with GDM: almost one-quarter of participants had GDM previously, which might limit the generalizability of the results. In addition, quantitative studies might not demonstrate the depth of data related to the experience of diagnosis; qualitative research would add to this description. Further research would benefit both from assessing the correlation of maternal demographic and risk perception with pregnancy outcome and from studying other populations and service modes. The strengths of the study include its multicultural sample of women, the relatively high participation rate, and the fact that it was performed during pregnancy, thereby reducing recall bias and eliminating bias related to events at the time of delivery.

In summary, the present study indicates that the multidisciplinary model of care provided to women with GDM is largely meeting their expectations for GDM diagnosis and education needs. It shows accurate understanding of treatment efficacy and risk perception. If the new diagnostic criteria are globally adopted, we must ensure that there are sufficient resources to meet the demand for education and treatment. Further clinical practice should emphasize the future risk of diabetes and focus on reducing this risk. The challenge remains to translate risk perception and understanding of lifestyle impact on the risk of T2DM into lifestyle change and prevention.

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Conflict of interest

The authors have no conflicts of interests.

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Chapter 5. Conclusion and future directions

5.1 Introduction

Obesity and excess GWG are independently associated with a number of short and long-term maternal and infant outcomes. Lifestyle interventions in pregnancy prevent excess GWG gain and reduce pregnancy complications. However, despite clear health needs and evidence for efficacy of lifestyle interventions, a major gap persists with inadequate translation of lifestyle change integrated into routine preconception and antenatal care. The central theme of my PhD was to address the effects of gestational weight gain and adverse maternal and infant outcomes, with development and implementation of strategies to achieve healthy pregnancies in high-risk women.

The final publication of my thesis, an invited editorial on the importance of gestational weight gain, forms the basis of my conclusion and provides recommendations for future research and translation to policy and practice. In this chapter, I draw together the key findings from each of the study phases and highlight the original contributions to the literature. Finally, overall implications and future directions for practice and research are outlined.

5.2 The importance of gestational weight gain

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Editorial: The importance of gestational weight gain.

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EDITORIAL

OBESITY Reviews WILEY

Editorial: The importance of gestational weight gain

Worldwide, rising adiposity in pregnancy has increasingly adverse health implications for the health of women and the next generation. Both pre-pregnancy body mass index (BMI) and gestational weight gain (GWG) are independent predictors of adverse pregnancy outcomes as highlighted in this issue by Stamm et al.[1] This underpins the 2009 US Institute of Medicine (IOM) updated guidelines[2] recommending healthy GWG targets across BMI categories. Specifically, IOM guidelines suggest GWG of 12.5–18 kg for those with pre-pregnancy BMI <18.5 kg/m^2 (women who are considered underweight); 11 .5–16 kg for 18.5–24.9 kg/m^2 (women who are considered normal weight); 7–11.5 kg for BMI 25–29.9 kg/m^2 (women who are considered overweight) and 5–9 kg for BMI ≥30 kg/m^2 (women who are considered to have obesity). Setting and reaching GWG targets therefore require accurate measurement of both BMI and GWG, yet major limitations exist in current approaches to these measurements as outlined in this issue by Stamm et al.[1]

Stamm et al. examine the important issue of bias in measures of GWG. Potential sources of bias include the accuracy of pre-pregnancy weight estimates and inconsistency of weight measurement prior to delivery. The authors highlight that current antenatal guidelines vary considerably and while most endorse measurement of weight, height and BMI at commencement of antenatal care, routine GWG monitoring recommendations, including frequency of monitoring, vary considerably.[3,4] Stamm et al. also discuss how bias can affect observed and reported relationships between GWG and adverse pregnancy outcomes and how that bias may be limited.[1] Measured pre-pregnancy weight is ideal to define healthy GWG, yet proxies include self-reported pre-pregnancy weight (within 12 months of pregnancy) or weight measured in the first trimester are often used. Overall, Stamm et al. found that mean differences in self-reported and measured pre-pregnancy weight were mostly less than 1 kg. However, using early pre-pregnancy weight rather than self-reported pre-pregnancy weight appears to reduce misclassification of BMI categories, 5–10% versus 6–30%, respectively. Likewise, total GWG is dependent on timing of final pregnancy weight measurement. and studies vary between using the last antenatal visit and delivery weight. We concur that measuring the final weight close to delivery and importantly adjusting for gestational age can reduce the bias.

Accurate measurement of GWG is important as this underpins our understanding of the complications of excess and insufficient weight gain. A recent systematic review and meta-analysis of 23 studies covering over 1.3 million pregnancies[5] explored associations between GWG below and above IOM guidelines, with maternal and infant health outcomes. Twenty-three percent of women gained below and 47% gained above GWG recommendations. Women who are considered underweight had the highest prevalence of GWG below guidelines (43%), whereas women who are considered overweight, followed by women who are considered to have obesity, had the highest prevalence of GWG above guidelines (64% and 60%, respectively). GWG below recommended was associated with a higher risk for small for gestational age (SGA), preterm birth and a lower risk of large for gestational age (LGA) and macrosomia. GWG above recommended was associated with a lower risk of SGA, preterm birth and a higher risk of LGA, macrosomia and caesarean section. A subgroup analysis on ethnicity, comparing Asia, the United States and Europe,[6] showed that women in the United States and Europe had higher pre-pregnancy BMI, higher prevalence of GWG above guidelines and a lower rate of GWG below guidelines, than women in Asia did. However, when applying Asian regional BMI categories, rates of GWG above guidelines and related clinical outcomes were similar across continents.

Moving beyond associations between GWG and pregnancy outcomes, lifestyle interventions also effectively reduce excess GWG and improve outcomes on systematic review and individual patient data (IPD) meta-analyses.[7] In data obtained from 36 randomized trials and including 12 526 women, antenatal lifestyle intervention reduced GWG by 0.7 kg (95% CI −0.92 to −0.48 kg) compared with controls and lowered the odds of caesarean section (0.91, CI 0.83 to 0.99). When supplemented with study level data from non-IPD studies, gestational diabetes (GDM) was reduced by 24% (0.76, 0.65 to 0.89), across 59 studies in over 16 thousand women. Intervention efficacy was similar irrespective of BMI, age, parity, ethnicity or pre-existing medical conditions. Similarly, GWG did not vary by intervention subtypes of diet, physical activity, mixed or other, highlighting the need to measure BMI accurately, establish GWG recommendations and intervene to reach these recommendations.

In a recent cost-effectiveness analysis, a low-intensity effective lifestyle intervention in antenatal clinical care compared with usual care showed estimated costs close to neutral, with an incremental cost effectiveness ratio of ∼1500 AUD per case of either GDM, hypertensive disorders of pregnancy or both, prevented. Low-intensity effective lifestyle interventions are likely to be cost-effective overall,[8] with further studies needed to elucidate effects by intervention type and impact on adverse outcomes prior to implementation and scale-up.[9]

Evidence now shows that meeting IOM GWG guidelines is associated with better pregnancy outcomes and that lifestyle intervention in pregnancy reduces excess GWG, improves pregnancy outcomes and may be cost effective. Yet implementing healthy lifestyle interventions into antenatal care requires us to overcome numerous implementation

barriers including consistent BMI measurement and GWG monitoring guidelines. We concur with Stamm et al. that consistent guidelines are clearly needed for GWG measurement.[10] Routine weighing appears acceptable to both women[11] and midwives,[12] but other barriers including time, resources and health provider knowledge and practice[13] need to be addressed to optimize implementation.

It is also important to note that setting BMI-based GWG targets, and monitoring GWG alone is inadequate to support lifestyle change, with women requiring additional lifestyle intervention support. Combining accurate BMI and GWG assessment with effective lifestyle intervention during pregnancy is effective in reducing GWG,[14,15] and there is a need to shift focus towards large-scale implementation of BMI and GWG assessment and of evidence-based lifestyle support, to improve outcomes for women and their children.

Improving assessment of BMI and GWG as recommended by Stamm et al. can also be augmented by novel emerging approaches to GWG monitoring. Algorithms are being derived from large-scale epidemiological modelling to personalize GWG recommendations. This approach relies on imputation from tens of thousands of pregnancies and can be applied regardless of timing and frequency of individual GWG measurement and may help address some of the issues raised by Stamm et al.

Overall, unhealthy lifestyle is driving high pre-pregnancy BMI, excess GWG and poor health outcomes in pregnancy and beyond. Current limitations in accuracy and consistency of pre-pregnancy BMI and GWG measurement present barriers to identifying those at risk and to optimizing lifestyle and GWG in pregnancy. Lifestyle interventions targeting recommended GWG by BMI category are known to improve health outcomes and may be cost-effective. Hence, addressing barriers to both assessment of BMI and GWG and to implementation of healthy lifestyle interventions in pregnancy is important to improve the health of women and the next generation.

CONFLICT OF INTEREST

No conflict of interest was declared.

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5.3 Key findings, overall implications and future direction and translation

This body of research has achieved its aim, and addresses important knowledge gaps in our understanding of GWG and obesity in pregnancy, and generates new insights into the risks associated with GWG outside of guidelines. It has contributed new knowledge in the new field of pragmatic trials and implementation research. Findings from my work have informed guidelines and current large-scale implementation trials targeting lifestyle interventions in pregnancy.

In chapter one, I summarised the existing literature on the prevalence, consequences and interventions for excess GWG. This enabled me to identify literature gaps that would inform my thesis research program.

In chapter two, I evaluated the maternal and infant risks associated with weight gain outside of the 2009 Institute of Medicine (IOM) recommendations. In this original research involving a systematic review, further original analysis and a meta-analysis of more than one million women internationally, 47% had GWG greater than IOM recommendations and 23% less than IOM recommendations. GWG below guideline recommendations was associated with a higher risk of SGA and preterm birth, and lower risk of LGA and macrosomia; weight gain above guideline recommendations was associated with lower risk of SGA and preterm birth and higher risk of LGA, macrosomia and caesarean. This work affirmed the US IOM guidelines for application internationally, including demonstrating applicability in the 60% of the world's population who are of Asian ethnicity. This work is highly cited and significantly influenced the recent national maternity-care guidelines underpinning recommendations to embed weighing and healthy lifestyle into routine care.

In chapter three, I developed, implemented and evaluated the Healthy Lifestyle in Pregnancy Project (HiPP) for Monash Health, designed to limit GWG for women with obesity in pregnancy. This pragmatic implementation trial evaluated an embedded, effective lifestyle intervention within an existing maternity service. Evaluation of the project took three forms: assessment of GWG, maternal and infant outcomes, health professionals' perspectives, and pregnant women's experiences. Lifestyle intervention embedded in routine antenatal care lowered total GWG and GWG/week, but did not alter proportion of women gaining above recommended GWG. Intervention uptake and engagement rates were high. This trial design and early learnings informed two other large international trials funded by the Global Alliance for Chronic Diseases. The next phase takes this lifestyle intervention, originally developed by my supervisors, across Asia with 1800 women now engaged in an implementation RCT. It also informed a recent Horizons 2020 and NHMRC implementation RCT to integrate some e-health component and to implement this across the EU and Australia.

In the qualitative evaluation of the HiPP project, I found that staff were supportive of the Healthy Pregnancy service and valued developing teamwork with staff and rapport with women. Most felt relatively comfortable discussing weight gain with women. Barriers included ability to navigate sensitive topics with women, limited awareness of the intervention among new staff, communication

between teams, and waiting time for women. In the mixed-methods analysis of pregnant women's experiences, women reported motivation to achieve a healthy lifestyle. During pregnancy, diet changes were reported as easier to make and sustain than exercise changes. Satisfaction with the service was high. Key factors identified in qualitative analysis were: service support enabled change; motivation to change behaviour; social support; barriers to making change (intrinsic, extrinsic and clinic-related); postpartum lifestyle and needs. On triangulation of data, qualitative and quantitative findings aligned. Together, these findings inform and improve implementation of service models integrating healthy lifestyle in the antenatal care of women with obesity.

In chapter four, I investigated satisfaction with diagnosis, risk perception and health beliefs to improve understanding of barriers and enablers of lifestyle change, to inform optimisation of treatment of GDM and prevent type II diabetes post GDM. It is important to include the experiences of women with GDM here. These women require significant input from allied health professionals and attend multiple additional appointments in their pregnancy. Understanding their experiences informed the development of Healthy Lifestyle in Pregnancy Project. These findings around risk perception and health beliefs in a high-risk group informed the planning of questionnaires and the qualitative component in chapter three.

This thesis has a number of strengths. I have completed a multi-method, focussed and in-depth programme of work, providing a strong evidence-base directly relevant the aim of my PhD. I begin the thesis by identifying gaps in the evidence-base, such as the role of ethnicity and challenges when comparing studies which have used different criteria for GWG. I completed a thorough systematic review and meta-analysis, requiring 13 study authors to re-analyse data for inclusion. Findings in such a large cohort and around inadequate GWG and ethnicity provided a novel contribution to the field. The Healthy Lifestyle in Pregnancy Project demonstrated the potential for benefit in a real-world setting when embedded into routine care. This novel finding is important for the implementation of policy and evidence into routine practice. Additionally, I have produced in-depth qualitative data alongside interventions, which is rarely reported. This detailed summary of real-world intervention is a novel contribution to the field.

There are limitations to note. In the second systematic review paper we were unable to explore ethnicity conclusively due to limitation of the provided data. I note that findings from the implementation study are from a single clinical service and need to be interpreted with this in mind.

Obesity and excess gestational weight gain is an increasing public health concern, with long-term implications for mother and child. RCTs have demonstrated that lifestyle interventions in pregnancy can reduce GWG as well as improve maternal and infant outcomes. The contemporary issues relate to implementation of services into the 'real-world' setting of routine antenatal care. Strong intervention should aim to achieve reach, penetration, participation, adherence and cost-effectiveness. Barriers to implementation are broad and require specialised services to appropriately deliver care to the target population. This work, along with cost-effectiveness studies will pave the way for international implementation.

Findings from this body of research have already been included in policy, practice and research; data from the systematic review have been included in updated national antenatal guidelines and findings from the Healthy Lifestyle in Pregnancy Project have informed an international implementation RCT. Recommendations for future policy, practice and research include the development of implementation studies to address the questions of: What is the optimal delivery and cost benefit analysis of implementation studies in real-life settings? What are the most effective components of the intervention? How can this service be scaled-up to help more women, with the aim of expanding to women with normal weight and overweight?

During my PhD, I have gained skills in systematic reviews and meta-analyses, in designing, implementing and evaluating a health service and in quantitative and quantitative analysis. In my next career steps I aim to utilise these skills and integrate clinical work with ongoing research to advance the implementation of healthy lifestyle in pregnancy care, with a specific focus on risk prediction and targeting of high-risk pregnancies and longer-term prevention of non-communicable diseases.

In conclusion, this thesis has addressed all stated aims. I have explored the effects of excess GWG on adverse maternal and infant health outcomes as well as the implementation of effective strategies to achieve healthy lifestyle and recommended weight gain in pregnancy. This has included the evaluation of experiences of high-risk women attending antenatal services, as well as health professionals' perspectives. I have presented novel data and provided findings to advance the field of maternal obesity and gestational weight gain, with data relating to clinical consequences, interventions and perspectives of health professionals and women.

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Appendix. Supplement to Publication 2.2

Supplementary Online Content

Goldstein RF, Abell SK, Ranasinha S, et al. Association of gestational weight gain with maternal and infant outcomes: a systematic review and meta-analysis. *JAMA*. doi:10.1001/jama.2017.3635

This supplementary material has been provided by the authors to give readers additional information about their work.

eAppendix 1. Search Terms

Searches	Results
Weight Gain/	23347
Pregnancy/	702831
1 and 2	3146
(weight and gain).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	57991
(weight and change).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	48999
4 or 5	100281
pregnan*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	775673
gestation*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	176589
7 or 8	822868
6 and 9	12406
3 or 10	12406
diabetes, gestational/ or fetal macrosomia/	7179
(gestational and diab*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	11182
gdm.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	2715
Pre-Eclampsia/	24030
pre-eclamp*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	26089
preeclamp*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	12721
Hypertension, Pregnancy-Induced/	1711
(gestational and hypertensi*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	6056
Postpartum Hemorrhage/	4842
(postpartum and hemorrhag*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	6438
(postpartum and haemorrhag*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	1573
obstetric labor, premature/ or premature birth/	18496
(preterm or pre-term).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	44753

(birth or labor or labour or deliver*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	730110
24 and 25	32432
cesarean section/ or extraction, obstetrical/ or vacuum extraction, obstetrical/ or labor, induced/	43512
(cesar* or caesar*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	52780
(induc* or instrument* or vacuum).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	2460462
25 and 29	95638
exp Resuscitation/	74306
exp thromboembolism/ or exp thrombosis/	142278
Intensive Care Units/	36416
Pregnancy/	702831
31 or 32 or 33	247846
34 and 35	8272
(resusc* or thrombo* or intensive care or (high and depend*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	763789
pregnan*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	775673
37 and 38	30807
failed instrumental delivery.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	17
Episiotomy/	1709
episiotomy.mp.	2330
anal sphincter injury.mp.	162
(third or fourth).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	379406
degree tears.mp.	120
44 and 45	103
12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 26 or 27 or 28 or 30 or 36 or 39 or 40 or 41 or 42 or 43 or 46	236364
exp Infant, Low Birth Weight/	26757
low birth weight.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	30133
small for gestational age.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	8085
exp Birth Weight/	34313
large for gestational age.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	1111
Congenital Hyperinsulinism/	303

((hypoglycem* or hypoglycaem*) and neonat*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	3013
Fetal Death/	22997
Respiratory Distress Syndrome, Newborn/	11479
(fet* or foet* or neonat*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	548601
(respiratory distress or death or intensive care).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	660039
57 and 58	74044
Intensive Care Units, Neonatal/	9922
shoulder dystocia.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	932
perinatal complication.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	46
birth trauma.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	838
umbilical cord ph.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	118
neonatal adiposity.mp.	38
48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 59 or 60 or 61 or 62 or 63 or 64 or 65	134946
47 or 66	331748
11 and 67	6168
limit 68 to (english language and female and humans and yr="1999 -Current")	2726

eAppendix 2. Additional Methods

Screening of search results

A trained clinician reviewer (RG) scanned the titles, abstract sections and keywords of every record retrieved by the search strategy in consultation with a highly experienced systematic reviewer (MM). Studies were selected and appraised by the reviewer in consultation with MM and clinical colleagues with evidence synthesis experience (HT) using study selection and appraisal criteria established *a priori*. Full articles were retrieved for all papers that met initial inclusion criteria, or if clarification was required beyond the abstract. In cases where selection was not clear, a second trained clinician reviewer appraised the paper (SA). Any discrepancies between the two appraisers was discussed with a third review author (MM).

Data extraction

Data were extracted from included studies using a specially developed data extraction form by two independent reviewers (RG, SA). Information collected included: type of study, study setting, study population, inclusion/exclusion criteria, outcomes measured and confounding factors. Missing data was obtained from the authors wherever possible. Any disagreement was resolved by discussion with an experienced biostatistician to reach a consensus (SR).

Data reanalysis request

Given the wide variation in classification of prepregnancy BMI categories and GWG categories, meaningful interpretation and meta-analysis was not possible. We therefore decided *a priori* to contact these authors to reanalyse and present data in a consistent, homogeneous format. For example, authors were requested to reclassify 1990 IOM GWG categories according to 2009 categories for data synthesis. If multiple weight gain groups within each BMI category were presented, authors were requested to reanalyse their data using 2009 categories.

Thirty one authors were contacted for data reanalysis and additional information, including the proportion of nulliparous women, proportion smoking in pregnancy, and mean maternal age for the meta-regression. This process involved email contact from the lead systematic review authors to the past senior study authors. Legal agreements for data sharing were prepared as well as authorship agreements where substantial reanalysis was required. Thirteen authors provided additional information and were included; eighteen did not provide this, of these three studies were still able to be included. Authors that were unable to reanalyse 1990 IOM data or correct multiple weight gain groups were excluded.

eTable 1. Descriptive Characteristics of 23 Included Studies

Study, year, country	Inclusion criteria	Exclusion criteria	Outcomes Measured	Confounders in original analysis	Provided additional data or reanalysis	Data for meta-analysis:
Durst[10] 2016 US	obese women; those delivering after 36 weeks gestation with documented weight in first trimester and within 10 days before delivery	NR	GDM, caesarean, chorioamnionitis, gestational HTN, preeclampsia, NICU admission, macrosomia, LGA, SGA	prior caesarean, age, race, parity, gestational age, payor status, tobacco use	no	adjusted
Enomoto[1] 2016 Japan	singleton pregnancy, successful delivery occurring at gestational week 22 or later	women with hypertension of diabetes, history of cervical conization, who delivered a newborn with congenital anomalies, missing data	pregnancy induced hypertension, GDM, macrosomia, SGA, LGA, preterm birth, spontaneous preterm birth, preterm premature rupture of membranes, induced preterm birth, caesarean	maternal age, height, parity and additional adjusting for clustering of deliveries by hospitals	no	adjusted
Hung[2] 2016 Taiwan	singleton pregnancy after 37 weeks gestation (cohort 2)	women with pregestational diabetes and hypertension, multiple gestations, fetal chromosomal or structural anomalies, fetal demise	GDM, preeclampsia, premature rupture of membranes, chroioamnionitis, placental abruption, placenta accreta, postpartum haemorrhage, operative vaginal delivery, severe perineal injury, primary caesarean, dysfunctional labour, malpresentation, abnormal FHR pattern, cephalopelvic disproportion, low birth weight, SGA, LGA, macrosomia, 1-min and 5-min Apgar scores <7, neonatal death, NICU	maternal age, parity, prior fetal death, prior preterm birth, conception methods, genetic amniocentesis, smoking in pregnancy, group B strep colonization, fetal sex, epidural	no	adjusted
Xiong[27,a] 2016 China	singleton, live-born, term pregnancies	women with diabetes, hypertension, heart disease before or during pregnancy or those with missing height and weight data, women who delivered a stillborn infant or infant with birth defects	Caesarean	maternal age, education, parity, fetal sex, birth weight	no	adjusted

eTable 1. Descriptive Characteristics of 23 Included Studies (continued)

Study, year, country	Inclusion criteria	Exclusion criteria	Outcomes Measured	Confounders in original analysis	Provided additional data or reanalysis	Data for meta-analysis:
Bogaerts[17] 2015 Belgium	singleton, live births	GW loss >45 kg, GWG > 60kg, extreme prepregnancy weight/height and weight at delivery	GDM, gestational hypertension, emergency caesarean, macrosomia, LGA, low birth weight, admission to NICU	parity, maternal age, gestational age	yes	crude
Shin[3] 2015 US	live births	missing prepregnancy BMI, GWG, preexisting DM and outcomes	gestational hypertension, GDM, preterm labour, SGA, LGA	maternal age, race, education, income, gestational age, WIC participation, smoking	yes	crude
Wen[21,a] 2015 China	singleton, age 18-40, normal prepregnancy BMI, GWG ≤ 16kg, primipara	GWG > 16kg, any DM, HT, severe congenital anomalies, missing data on BMI, GWG, birth weight or pregnancy outcomes	Preterm, birthweight, gestational age, mode of delivery, Apgar score, NICU, duration of hospital stay	income, maternal education, occupation, weight gain advice, residential area	no	adjusted
Yang[22,a] 2015 China	singleton, live birth, gestational age ≥ 28 wk	NR	low birth weight, macrosomia	maternal age, maternal education, infant gender (provided crude and adjusted)	no	crude
Badon[13] 2014 US	pregnant women < 31 weeks gestation	age < 18, multiple pregnancy, previous diabetes, diabetes in pregnancy	skin folds > 90th percentile, birthweight >90th percentile, body fat >90th percentile, cord serum C-peptide >90th percentile for gestational age	gender, race, parity, study centre, maternal age, OGTT z score sum, alcohol use, smoking, family history of diabetes, hospitalisation pre delivery gestational age at last prenatal weight and OGTT mean arterial pressure at OGTT, maternal height	no	adjusted
Chihara[15] 2014 US	NR	no prenatal record, gestational age <20 or >44 wk, multiple births, missing GWG, birthweight	low birth weight, macrosomia	maternal age, education, race/ethnicity, marital status, smoking status, parity	no	adjusted
Haugen[44,b] 2014 Norway	prepregnancy weight and height, weight at delivery and 6 months post partum	gestation < 37 or > 42 wk, GWG < -30kg or > 50kg, age < 18 years, women with 2nd or 3rd participation in study	macrosomia, gestational hypertension, preeclampsia, emergency caesarean section	maternal age, maternal height, maternal education, gestational length, smoking, diabetes	yes	crude

eTable 1. Descriptive Characteristics of 23 Included Studies (continued)

Study, year, country	Inclusion criteria	Exclusion criteria	Outcomes Measured	Confounders in original analysis	Provided additional data or reanalysis	Data for meta-analysis:
Lee[12,d] 2014 Korea	singleton, live births	pre-existing medical conditions (diabetes and HT)	LGA	maternal age, parity	yes	crude
Swank[20] 2014 US	singleton, live birth, gestation 24-42 (+6) wk	unknown prepregnancy BMI	GDM, gestational hypertension, caesarean, preterm < 34 weeks, macrosomia	maternal age, parity, race, hypertension, pregestational diabetes	yes	crude
Black[5] 2013 US	singleton, live birth gestation ≥ 20 wk	those requiring treatment for GDM	LGA (provided additional outcomes in reanalysis incl. SGA, preterm, macrosomia and caesarean section)	maternal age, race/ethnicity, parity, infant sex, presence of PE/E	yes	crude
Kominiarek[18,c] 2013 US	BMI ≥ 30 kg/m², singleton, live birth, ≥ 37 wk, known GWG	weight loss > 20kg, weight gain > 50kg	operative vaginal delivery, nulliparas and multiparas caesarean, postpartum haemorrhage, SGA infants, LGA infants, low birth weight, macrosomia, shoulder dystocia, Apgar, NICU admission	age, race/ethnicity, marital status, insurance, parity, smoking, gestational age	yes	adjusted
Li[6,e] 2013 China	mother-child pairs with information and clinical measurements	multiple births, stillbirths, multiparous women, missing variables	GDM, pregnancy induced hypertension, caesarean, preterm delivery, LGA, SGA macrosomia, low birth weight	maternal age, maternal height, maternal education, smoking, family income, maternal occupation, gestational age	yes	crude
Di Benedetto[14] 2012 Italy	Caucasian women, had glucose challenge test	gestation < 37 weeks, twin pregnancy, glucose intolerance in pregnancy, missing delivery information	macrosomia, caesarean	gestational age at delivery, glycaemia	yes	crude
Moore Simas[7] 2012 US	singleton, live birth	congenital anomaly, missing prepregnancy weight, height, GWG, unknown neonate gender or weight, gestation < 22 wk or > 44 wk	SGA, LGA	both crude and adjusted. marital status, race, parity, smoking, diabetes, hypertension	yes	crude

eTable 1. Descriptive Characteristics of 23 Included Studies (continued)

Study, year, country	Inclusion criteria	Exclusion criteria	Outcomes Measured	Confounders in original analysis	Provided additional data or reanalysis	Data for meta-analysis:
Blomberg[19] 2011 Sweden	BMI ≥ 30 kg/m², singleton, live birth, ≥ 37 wk	extreme GWG or GW loss	pre-eclampsia, instrumental delivery, caesarean, post partum haemorrhage, LGA, SGA, fetal distress	maternal age, parity, smoking	no	adjusted
J Park[8,d] 2011 Korea	live births, gestation 28-42 weeks	missing prepregnancy BMI, hypertension, diabetes, twin pregnancy, congenital anomaly, previous caesarean	SGA, LGA, macrosomia, caesarean section, preterm birth, preeclampsia, anemia, GDM (OR only calculated for BMI, not GWG)	both crude and adjusted. BMI, smoking, parity, education, husband's education, gestational age, gestational diabetes	yes	crude
S Park[9] 2011 US	singleton, live birth, gestational 37-41 wk, age 18-40 years	chronic diabetes, chronic hypertension, missing information for BMI, GWG, LGA or SGA status	SGA, LGA	maternal age, parity, gestational age, education, smoking, WIC program participation, total number of prenatal visits, infant sex, infant birth year	yes	crude
Vesco[11] 2011 US	prepregnancy weight, delivery weight, height	diabetes (gestational and pregestational), hypertension	macrosomia, LGA, SGA	age, BMI, gestation, race, parity smoking, Medicaid (provided crude and adjusted)	no	crude
Rode[16] 2007 Denmark	age > 18 years, Danish speaking, no alcohol or drug abuse, completed both questionnaires	multiple gestations, gestational age < 37 weeks, missing infant birth weight	birth weight > 3000g and > 4000g	smoking status	yes	crude

Key

a	data according to Chinese BMI categories only
b	sample size changed when provided additional data
c	sample size changed when provided additional data, OR not recalculated
d	data according to both Korean and WHO BMI categories (WHO reported here)
e	data according to Chinese and WHO BMI categories (WHO reported here)
NR	not reported

eTable 2. Range of Total Event Rates per Live Birth for Primary and Secondary Outcomes

Outcome	GWG compared to guidelines	Median event rate per live births	Interquartile range		Minimum no. of events	Maximum no. of events	No. (%) of studies included in pooled estimate	No. (%) of participants included in pooled estimate
SGA	GWG below	156	58	1987	1	11213	6/11 (54.5)	768692/1019805 (75.4)
	GWG within	179	54	1254	6	10324		
	GWG above	114	38	865	3	8460		
LGA	GWG below	87	15	363	2	16571	6/13 (46.2)	768692/1041399 (73.8)
	GWG within	209	49	914	10	6183		
	GWG above	274	107	1370	2	15146		
Preterm birth	GWG below	90.5	20.5	353.5	1	5891	3/4 (75.0)	140965/360833 (39.1)
	GWG within	76.5	41	203.5	2	994		
	GWG above	72.5	33	129.5	1	248		
Macrosomia	GWG below	19	14	145	3	782	5/11 (45.5)	208020/241665 (86.1)
	GWG within	63	35	214	4	2573		
	GWG above	111	37	687	3	4014		
Caesarean	GWG below	184	62	726	6	12446	5/8 (62.5)	208020/218207 (95.3)
	GWG within	327	151	945	14	5645		
	GWG above	617	197	1119	13	8208		

eTable 3. Absolute Risk Difference (ARD) for Studies That Stratified by Prepregnancy Underweight (BMI <18.5 kg/m²), Normal Weight (18.5-24.9kg/m²), Overweight (25-29.9 kg/m²) and Obese (≥ 30 kg/m²)

		GWG below guidelines			GWG above guidelines		
Outcome	**Prepregnancy BMI category**	ARD (%)	Confidence interval (%)	p-value	ARD (%)	Confidence interval (%)	p-value
SGA	**Underweight**	8	6, 11	<0.0001	-6	-8,-3	<0.0001
	Normal weight	5	4,6	<0.0001	-2	-3,-1	<0.0001
	Overweight	3	3,4	<0.0001	-3	-4,-2	<0.0001
	Obese	2	2,3	<0.0001	-2	-3,-1	<0.0001
	Combined	**5**	**4,6**	**<0.0001**	**-3**	**-4,-2**	**<0.0001**
LGA	**Underweight**	-3	-5,-1	0.016	4	4,5	<0.0001
	Normal weight	-3	-4, -2	<0.0001	6	5,7	<0.0001
	Overweight	-11	-33,10	0.29	-2	-14,9	0.68
	Obese	13	-34,60	0.59	7	5,8	<0.0001
	Combined	**-2**	**-10,-6**	**<0.0001**	**4**	**2,5**	**<0.0001**
Preterm	**Underweight**	8	1,15	0.03	-1	-3,0	0.07
	Normal weight	6	0, 11	0.03	-1	-2,0	0.01
	Overweight	4	-1,9	0.08	-3	-5,-1	0.01
	Obese	3	1,5	0.01	-2	-5,2	0.30
	Combined	**5**	**3,8**	**<0.0001**	**-2**	**-2,-1**	**<0.0001**
Macrosomia	**Underweight**	-1	-3,0	0.07	3	2,4	<0.0001
	Normal weight	-2	-5,1	0.14	10	5,15	<0.0001
	Overweight	-2	-6,2	0.34	5	1,10	0.01
	Obese	-3	-4,-2	<0.0001	6	1,12	0.03
	Combined	**-2**	**-3,-1**	**<0.0001**	**6**	**4,9**	**<0.0001**
Caesarean	**Underweight**	1	-2,4	0.67	6	5,12	0.02
	Normal weight	0	-4,3	0.82	0	-4,3	0.82
	Overweight	1	0,3	0.13	1	0,3	0.13
	Obese	-2	-5,1	0.11	-2	-5,1	0.11
	Combined	**0**	**-2,1**	**0.80**	**4**	**3,6**	**<0.0001**

eTable 4. Absolute Risk Difference (ARD) for Studies That Stratified by Prepregnancy Obesity Class 1 (30-34.9 kg/m²), Class 2 (35-39.9 kg/m²) and Class 3 (≥40 kg/m²)

		Weight loss			GWG below guidelines			GWG above guidelines		
Outcome	**Prepregnancy obesity category**	ARD (%)	Confidence interval (%)	p-value	ARD (%)	Confidence interval (%)	p-value	ARD (%)	Confidence interval (%)	p-value
SGA	**Class 1, 2 and 3**	3	1,5	0.001	1	1,1	<0.0001	-1	-2,0	0.003
LGA	**Class 1, 2 and 3**	-5	-7,-3	<0.0001	-2	-3,-1	<0.0001	5	5,6	<0.0001
Macrosomia	**Class 1, 2 and 3**	-5	-9,-2	0.004	-2	-3,0	0.04	3	0,6	0.02
Caesarean	**Class 1, 2 and 3**	-4	-6,-3	<0.0001	-2	-3,-1	0.0001	2	0,3	0.03

eTable 5. Metaregression*

eTable 5a. Small for gestational age (SGA): GWG below guidelines

Variable (log OR)	Coefficient	p-value	Lower CI	Upper CI	I²	p-value
Smoking (yes)	0.0168061	0.275	-0.0144823	0.480945		
Mean maternal age (years)	-0.0261548	0.499	-0.1056045	0.0532949	82.40	0.5648
Nulliparous (yes)	0.005939	0.850	-0.0059076	0.0070954		

eTable 5b. Small for gestational age (SGA): GWG above guidelines

Variable (log OR)	coefficient	p-value	Lower CI	Upper CI	I²	p-value
Smoking (yes)	-0.0134361	0.229	-0.0360401	0.0091678		
Mean maternal age (years)	0.0012392	0.961	-0.0504527	0.0529311	56.69	0.6140
Nulliparous (yes)	-0.0022508	0.258	-0.0062862	0.0017846		

eTable 5c. Large for gestational age (LGA): GWG below guidelines

Variable (log OR)	coefficient	p-value	Lower CI	Upper CI	I² (%)	p-value
Smoking (yes)	-0.0043308	0.764	-0.0339869	0.0253254		
Mean maternal age (years)	-0.0285584	0.373	-0.0939485	0.0368317	80.09	0.7824
Nulliparous (yes)	-0.0012528	0.635	-0.0066767	0.0041711		

eTable 5d. Large for gestational age (LGA): GWG above guidelines

Variable (log OR)	coefficient	p-value	Lower CI	Upper CI	I^2	p-value
Smoking (yes)	-0.0434918	0.018	-0.078729	-0.0082546	62.85	0.0438
Mean maternal age (years)	0.0559416	0.123	-0.0166145	0.1284978		
Nulliparous (yes)	-0.0020981	0.498	-0.0084533	0.00425921		

eTable 5e. Preterm: GWG below guidelines

Variable (log OR)	coefficient	p-value	Lower CI	Upper CI	I^2	p-value
Smoking (yes)	0.0040798	0.981	-0.4492887	0.4574483		
Mean maternal age (years)	-0.3681926	0.031	-0.6822238	-0.0541615	0	0.0897
Nulliparous (yes)	-0.0036068	0.732	-0.0308255	0.0236119		

eTable 5f. Preterm: GWG above guidelines

Variable (log OR)	coefficient	p-value	Lower CI	Upper CI	I^2	p-value
Smoking (yes)	0.0238088	0.890	-0.4248947	0.4725123		
Mean maternal age (years)	-0.0322376	0.844	-0.4592485	0.3947733	37.51	0.9598
Nulliparous (yes)	0.0024824	0.791	-0.0218696	0.0268343		

eTable 5g. Macrosomia: GWG under guidelines

Variable (log OR)	coefficient	p-value	Lower CI	Upper CI	I^2	p-value
Smoking (yes)	-0.0149201	0.120	-0.0341692	0.0043291		
Mean maternal age (years)	-0.053015	0.294	-0.1563202	0.0502902	45.85	0.3093
Nulliparous (yes)	-0.0041864	0.168	-0.0103212	0.0019485		

eTable 5h. Macrosomia: GWG above guidelines

Variable (log OR)	coefficient	p-value	Lower CI	Upper CI	I^2	p-value
Smoking (yes)	-0.0048213	0.704	-0.0311867	0.0215442		
Mean maternal age (years)	0.0998829	0.302	-0.0982192	0.2979851	38.36	0.3580
Nulliparous (yes)	0.0064108	0.164	-0.0028977	0.0157193		

eTable 5i. Caesarean section: GWG under guidelines

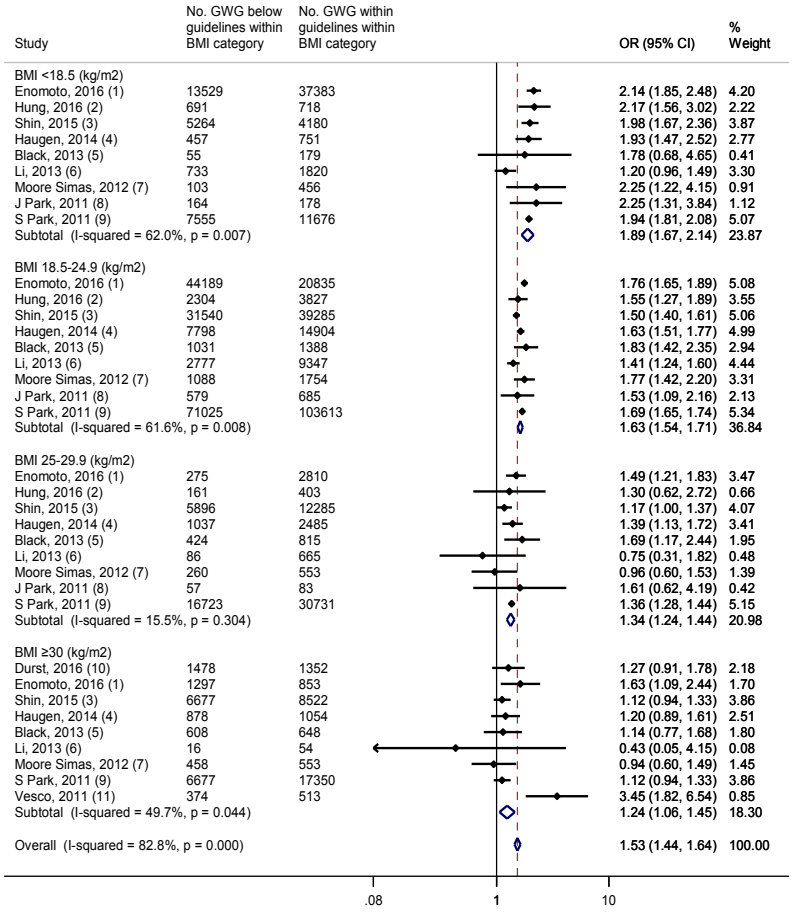
Variable (log OR)	coefficient	p-value	Lower CI	Upper CI	I^2	p-value
Smoking (yes)	0.002462	0.865	-0.0276761	0.0326001		
Mean maternal age (years)	0.0037539	0.937	-0.0953004	0.1028081	37.17	0.9128
Nulliparous (yes)	0.0013454	0.548	-0.003298	0.0059888		

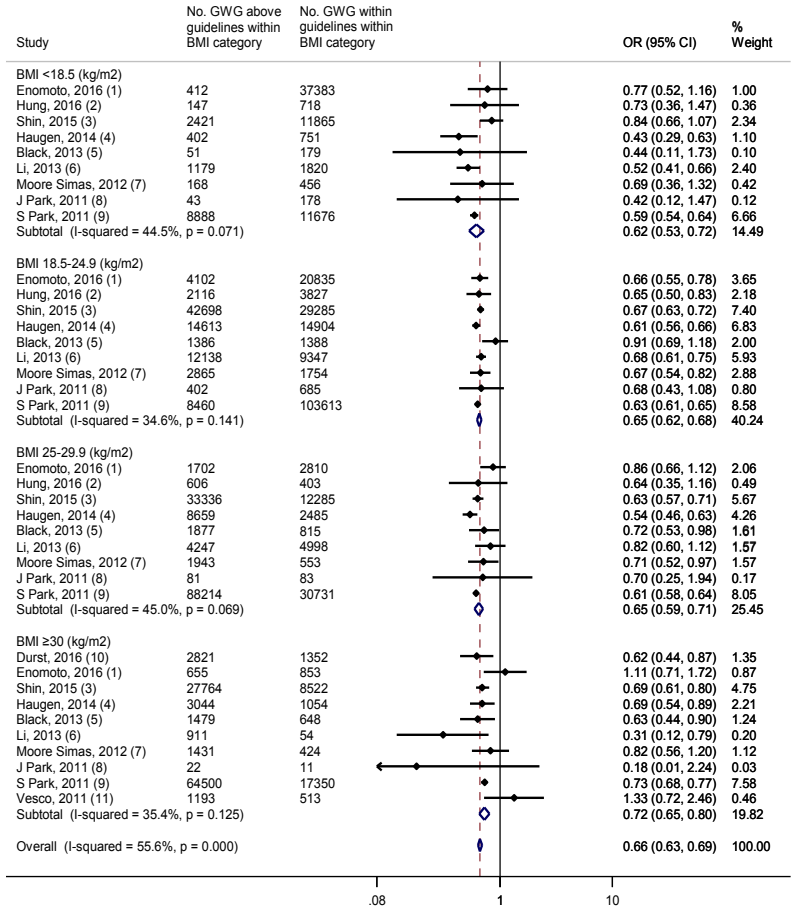
*REML estimate of between-study variance % residual variation due to heterogeneity. Proportion of between-study variance is explained using the Joint test for all covariates with Knapp-Hartung modification

eFigure 1. Pooled OR for Primary and Secondary Outcomes

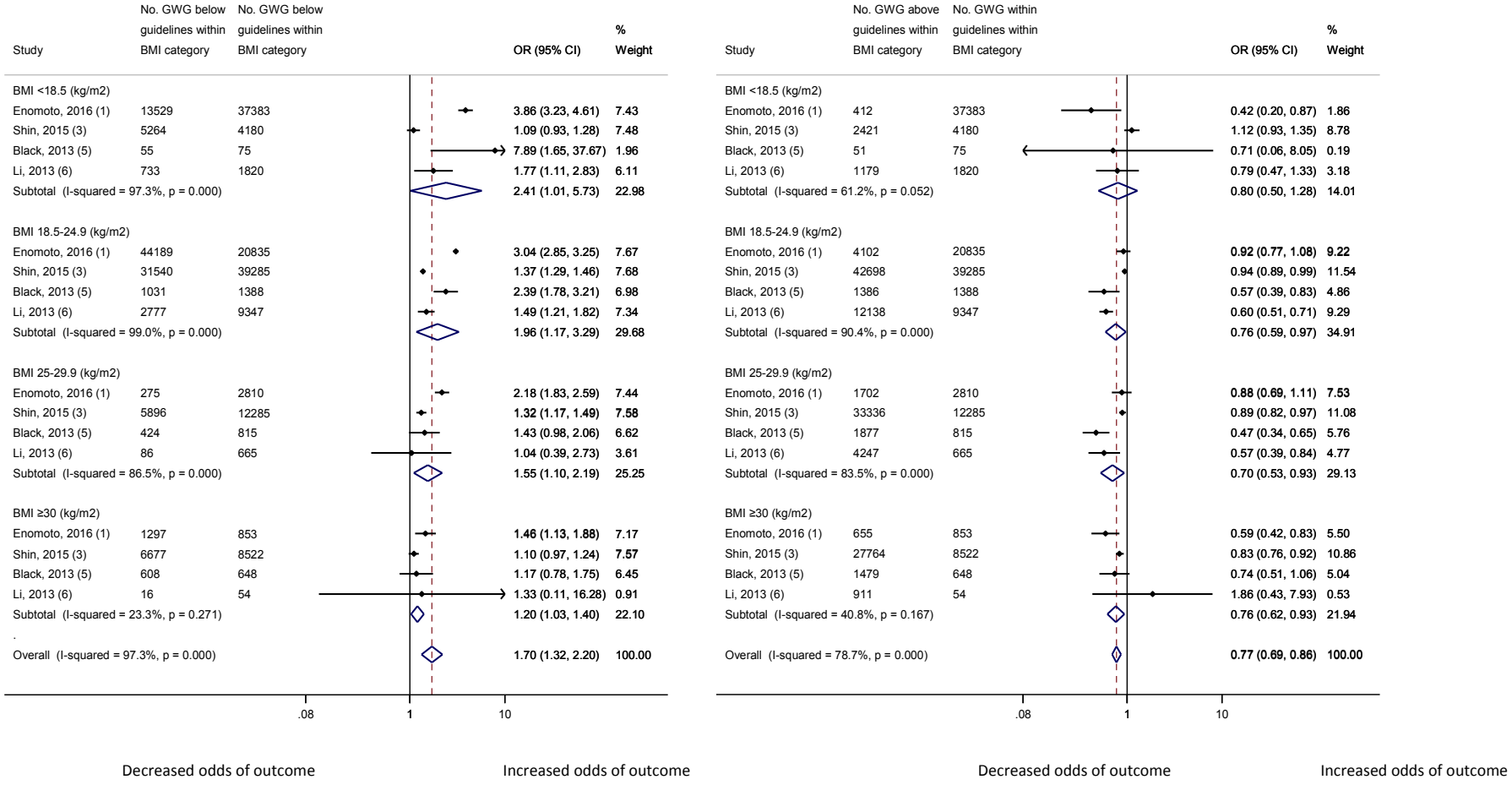
Reference group = women with recommended weight gain in each BMI group

eFigure 1a. Small for gestational age (SGA)

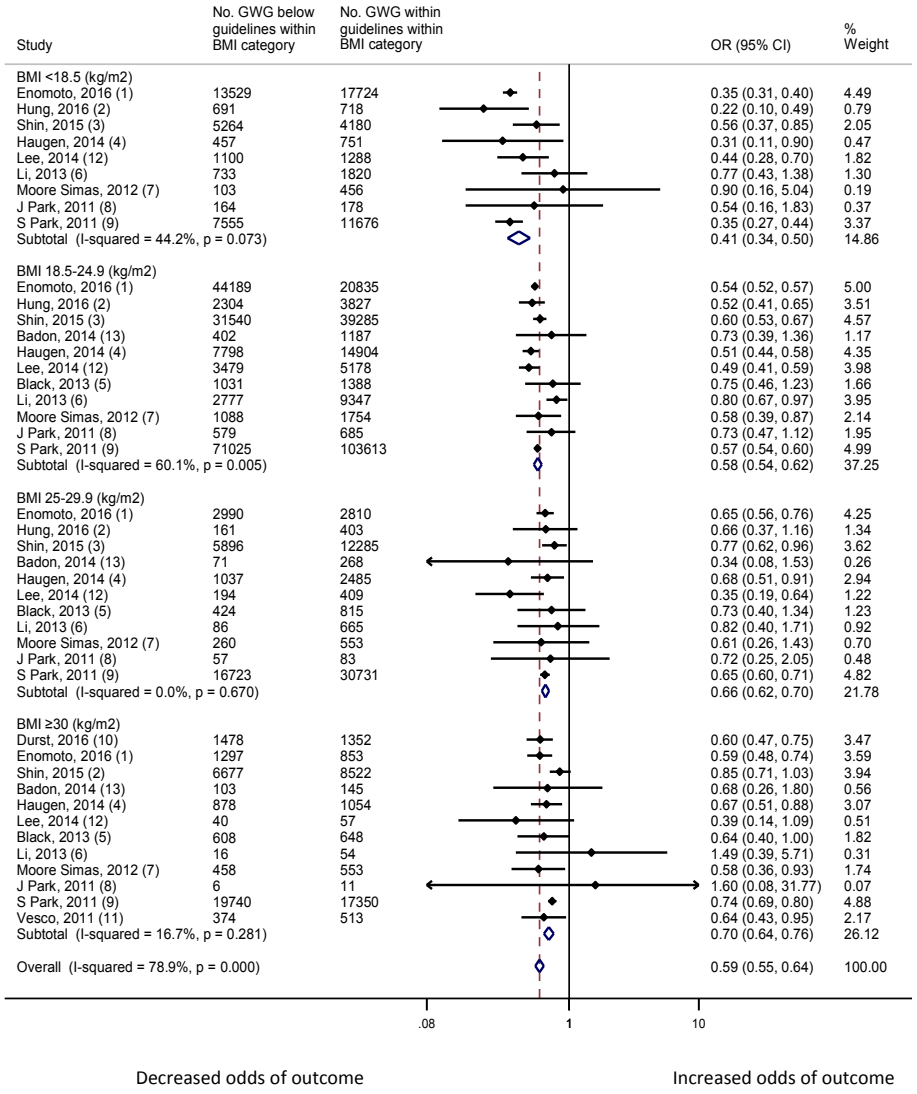


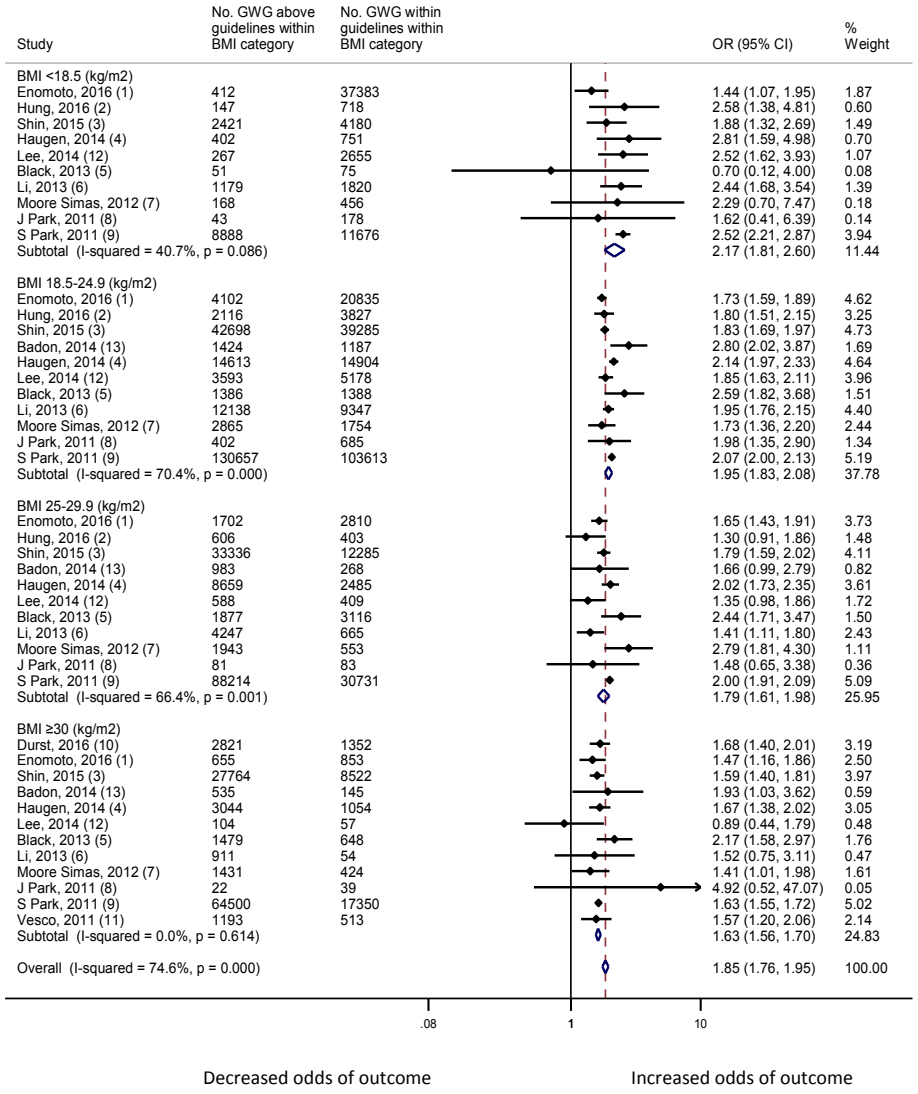


eFigure 1b. Preterm birth

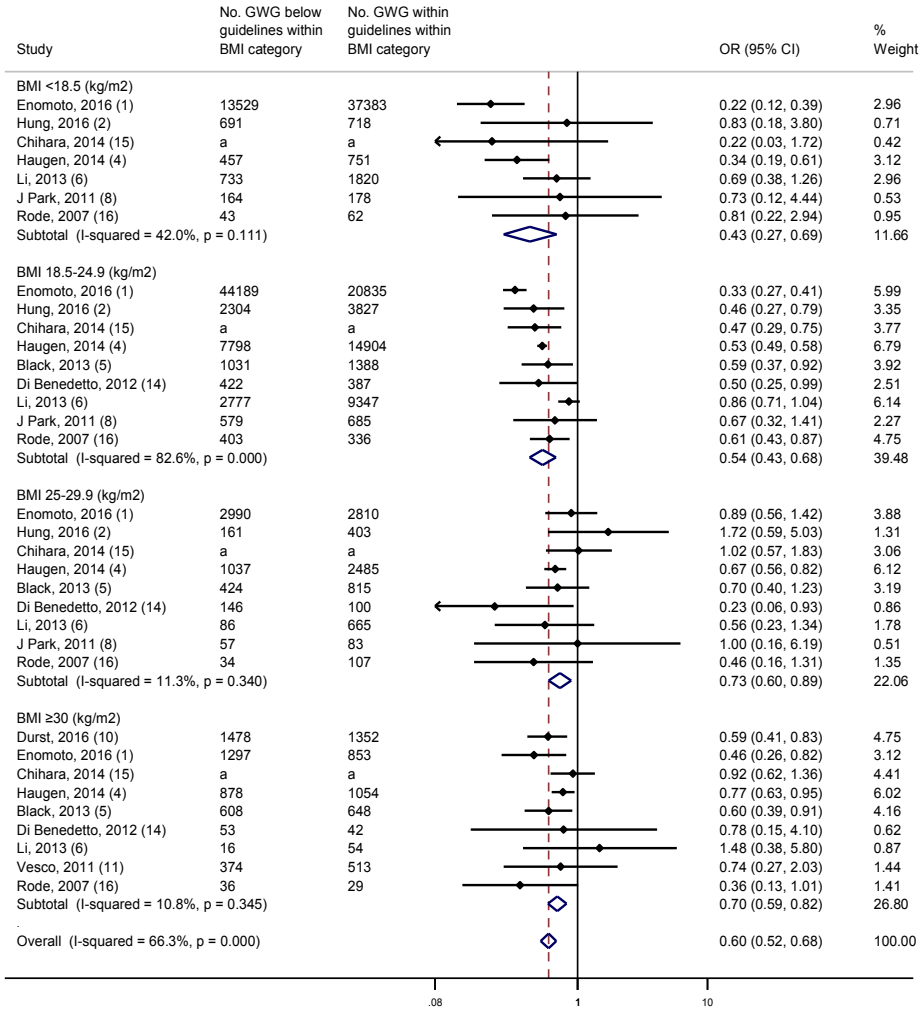


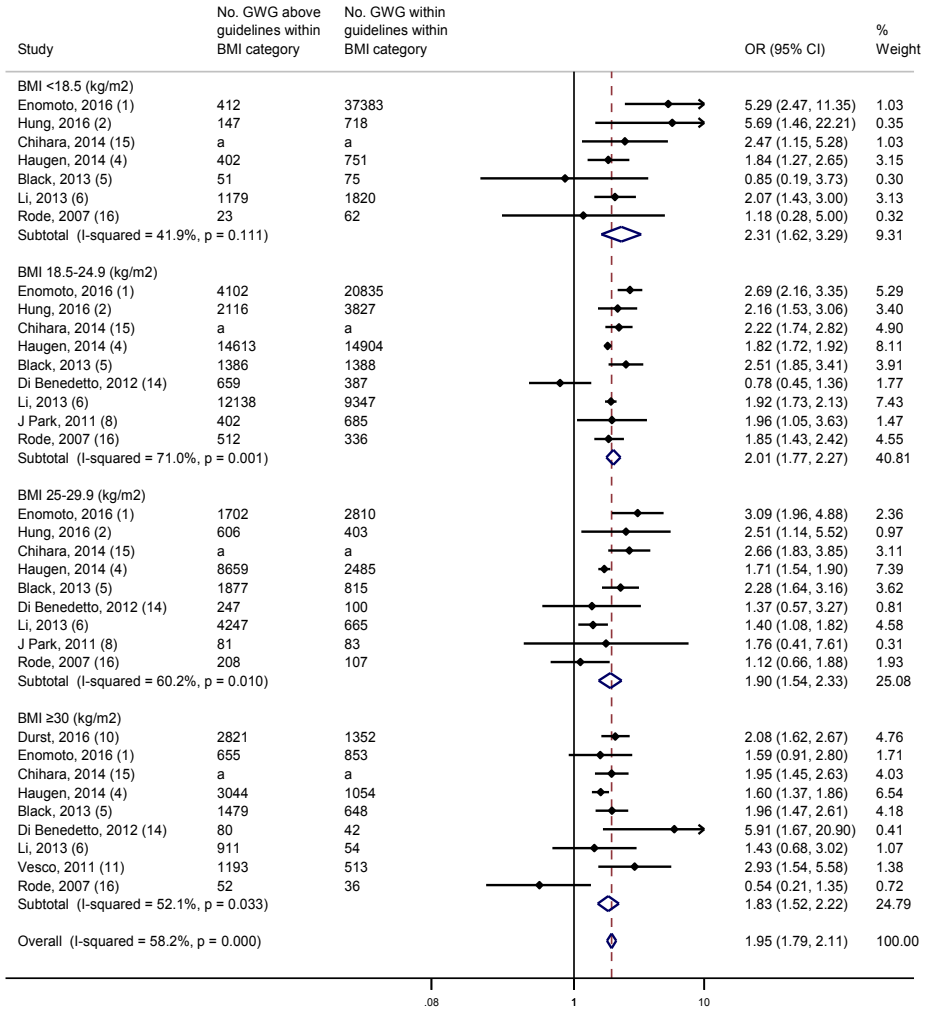
eFigure 1c. Large for gestational age (LGA)



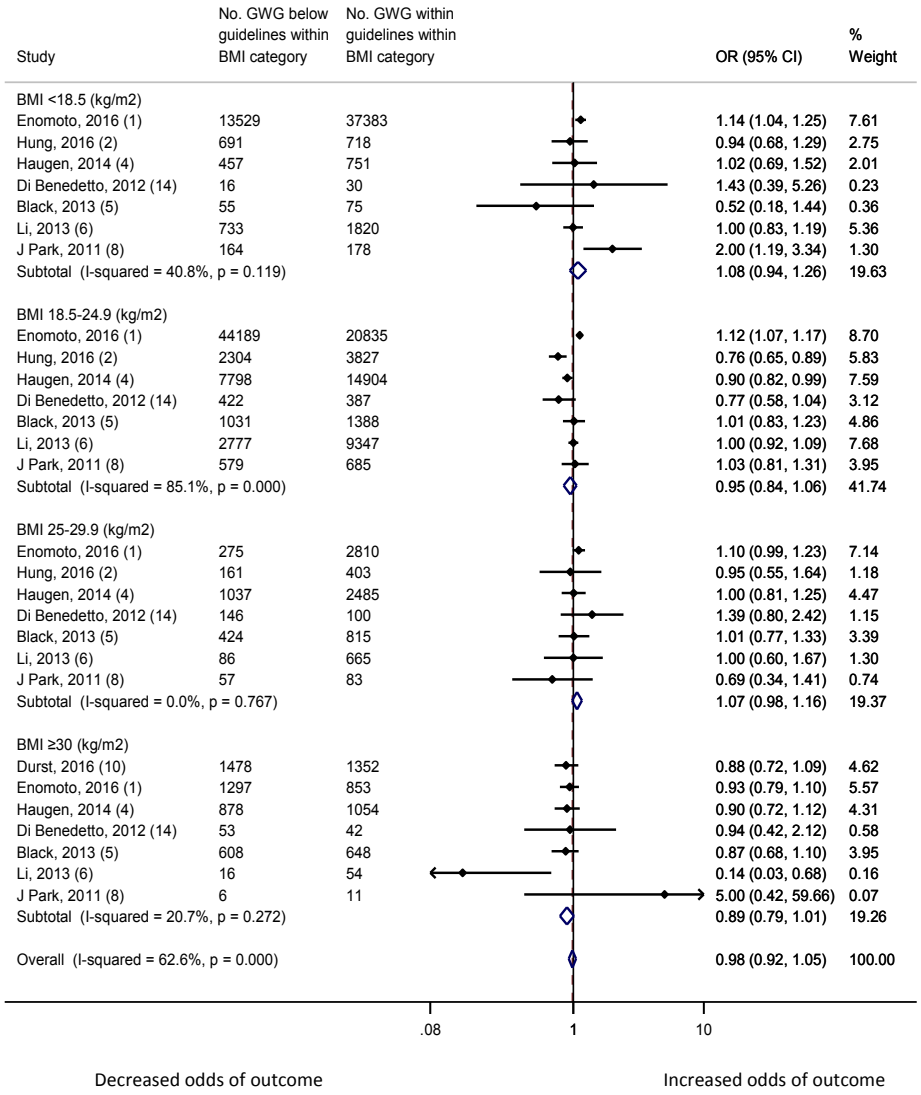


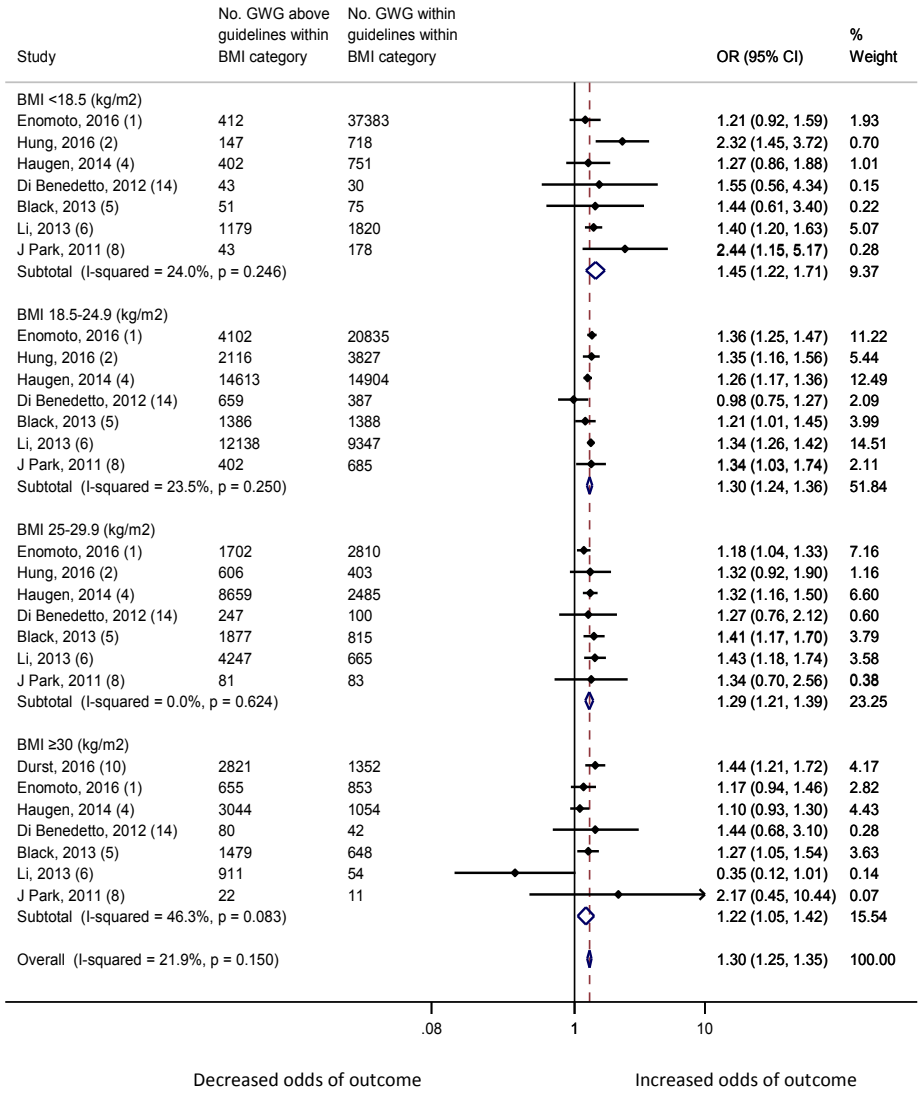
eFigure 1d. Macrosomia





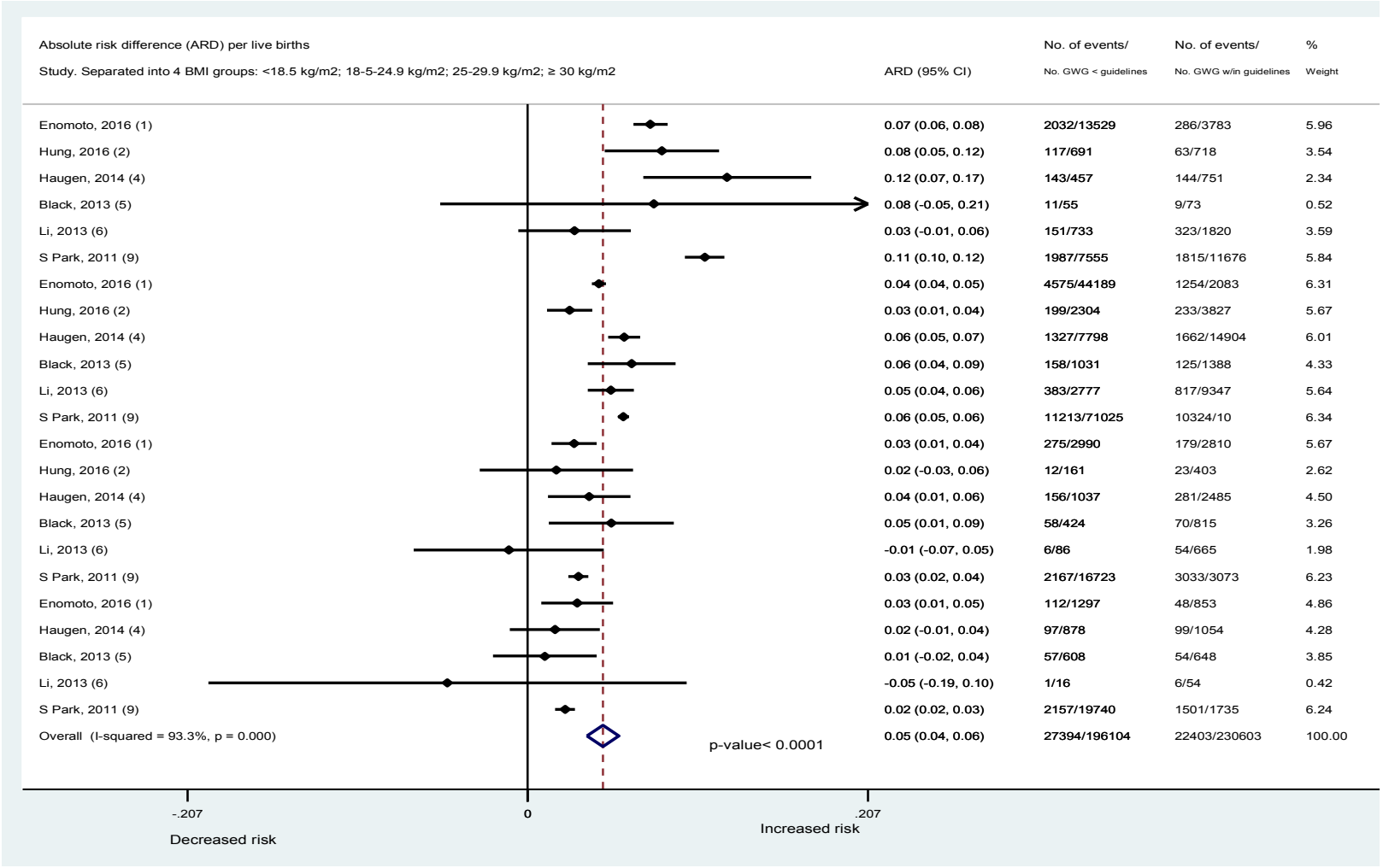
eFigure 1e. Caesarean section



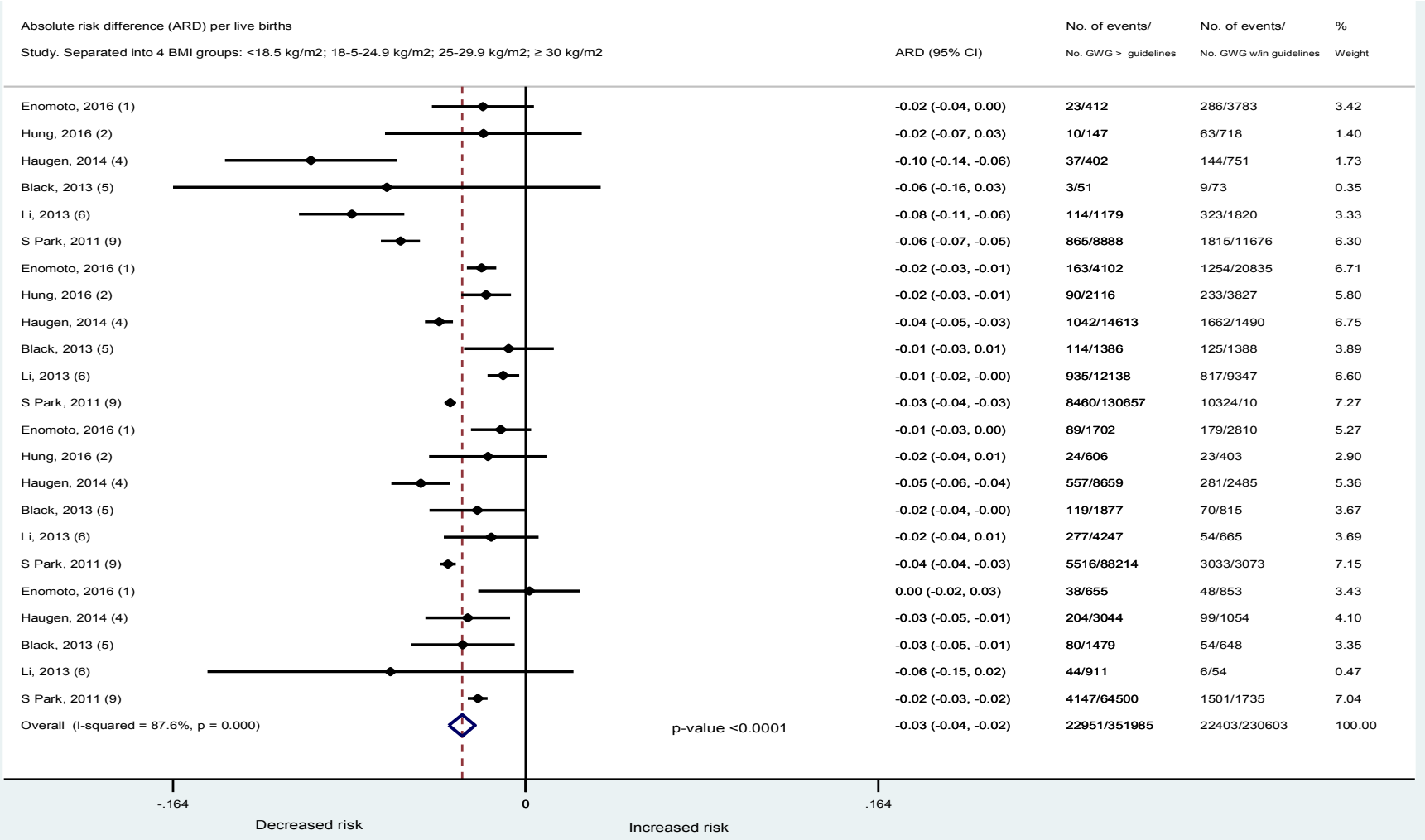


eFigure 2. Absolute Risk Difference Plots (per Live Birth)

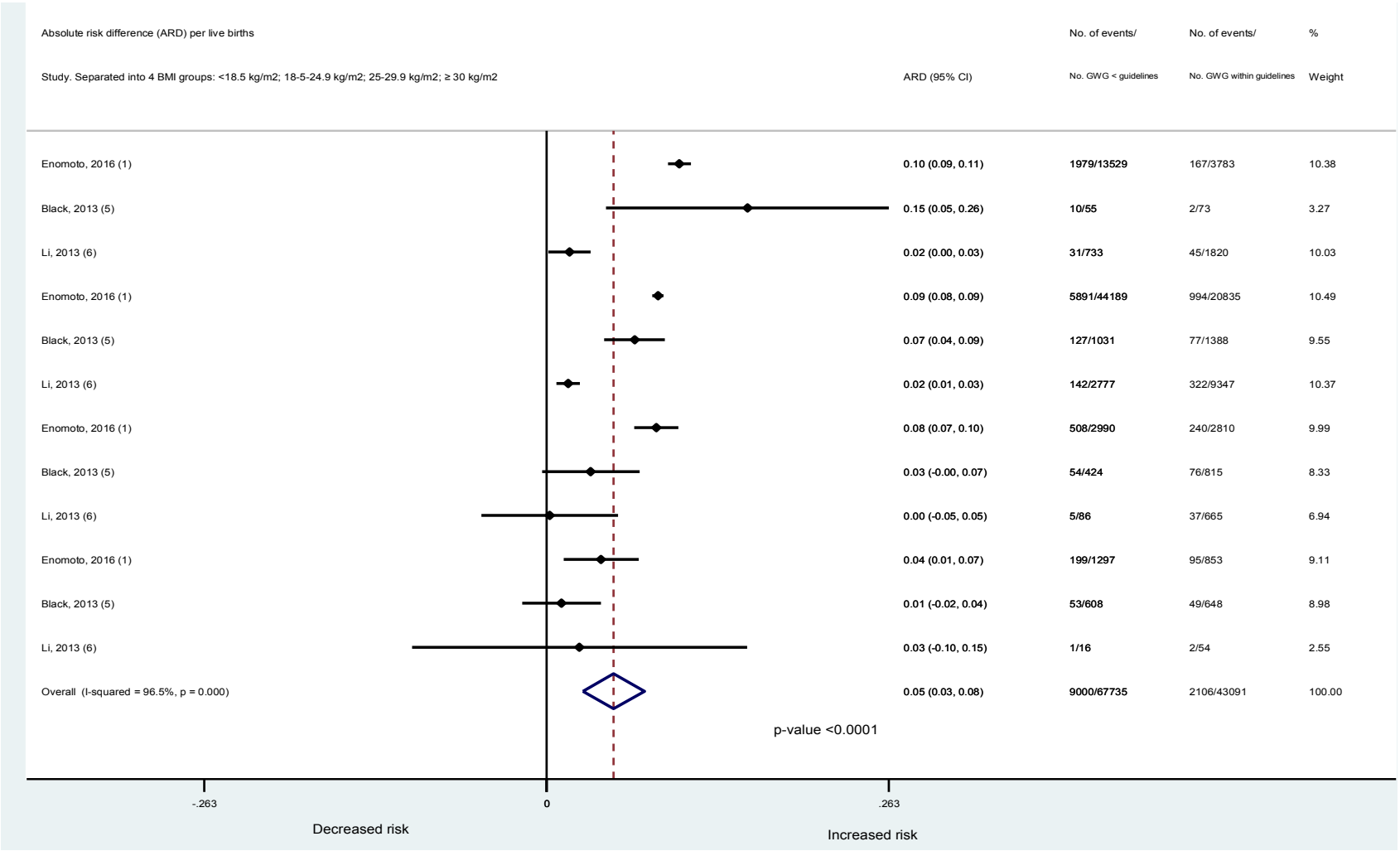
eFigure 2a. Small for gestational age (SGA): GWG below guidelines (all BMI groups combined)



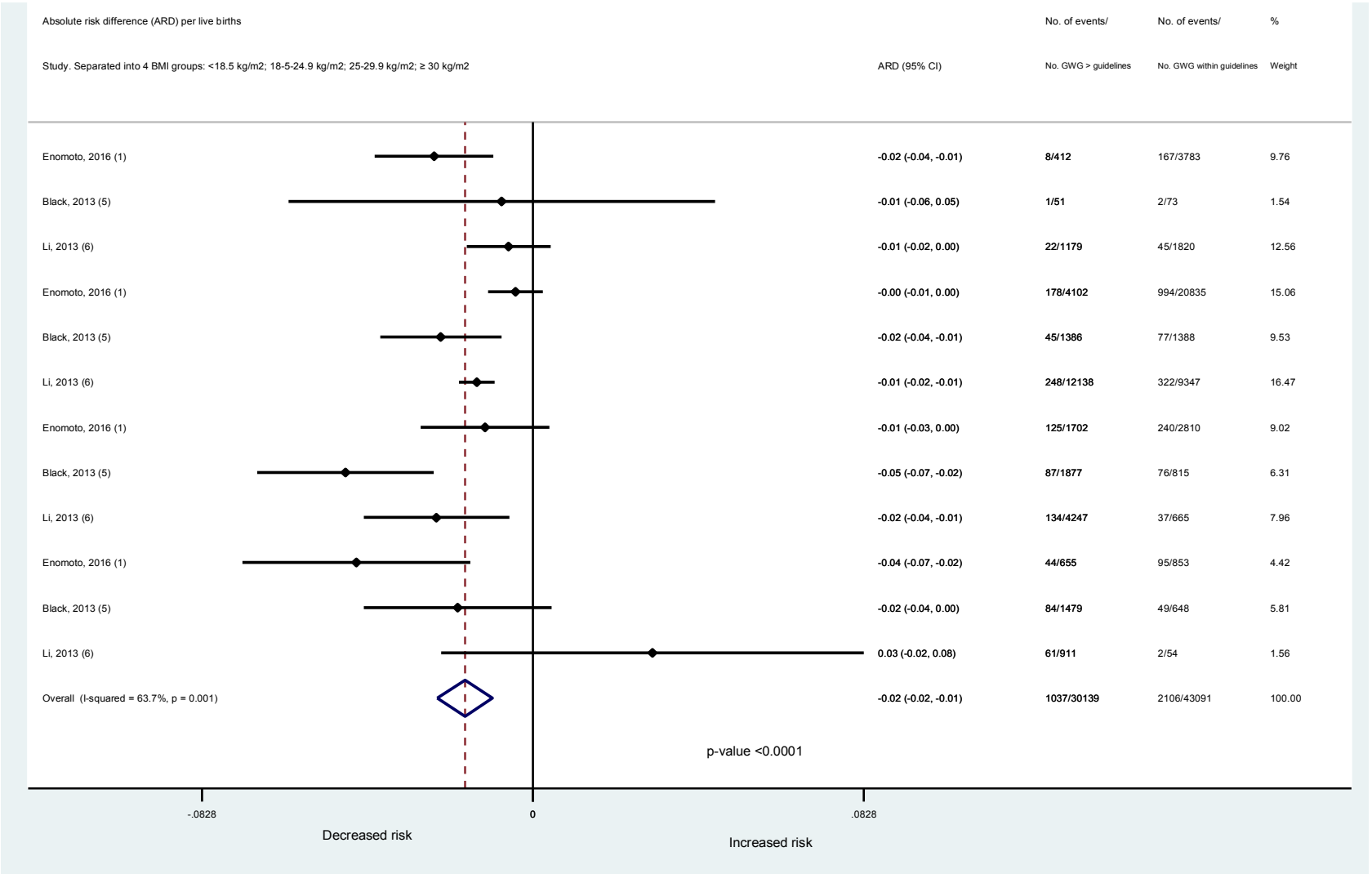
eFigure 2b. Small for gestational age (SGA): GWG above guidelines (all BMI groups combined)



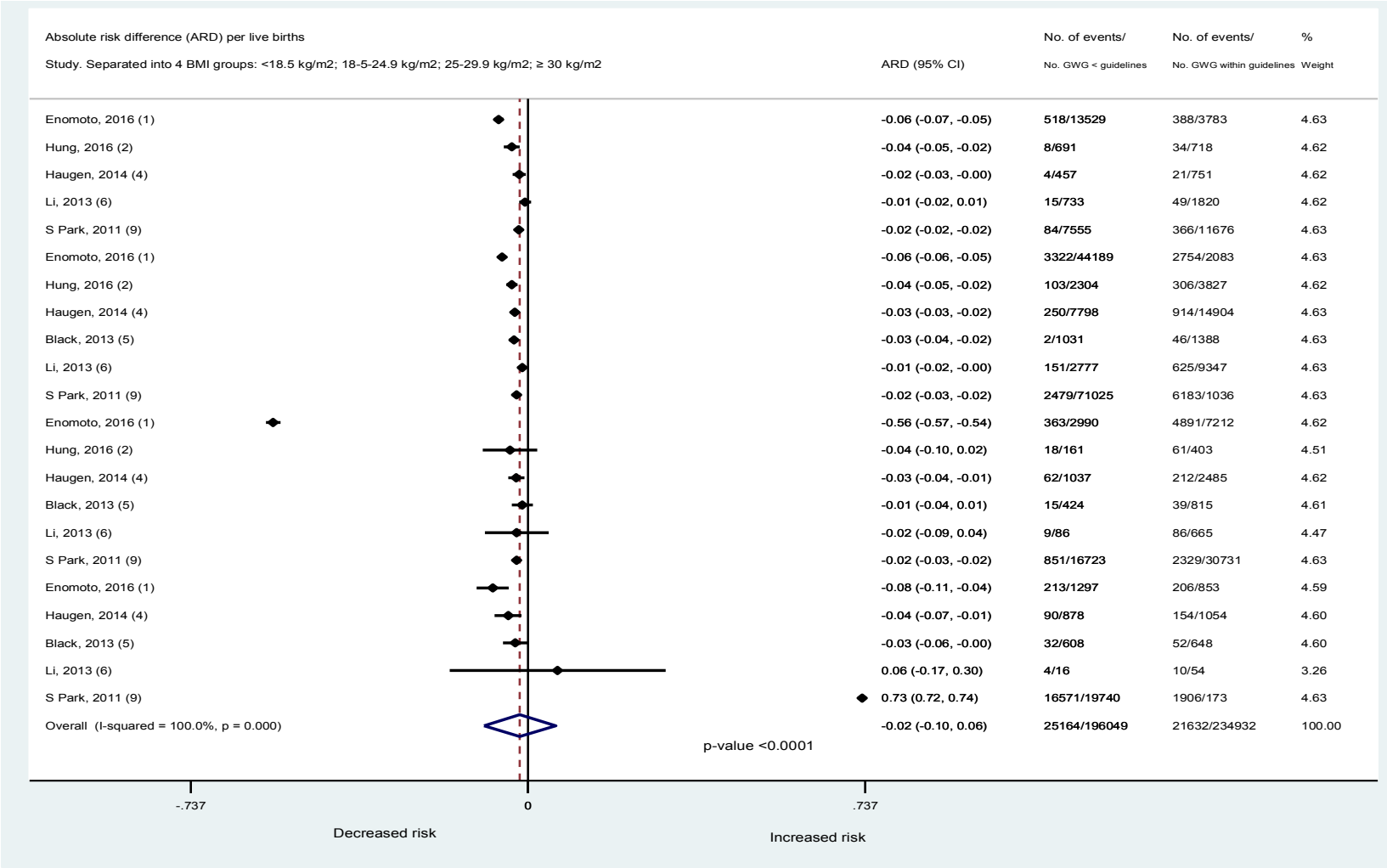
eFigure 2c. Preterm birth: GWG below guidelines (all BMI groups combined)



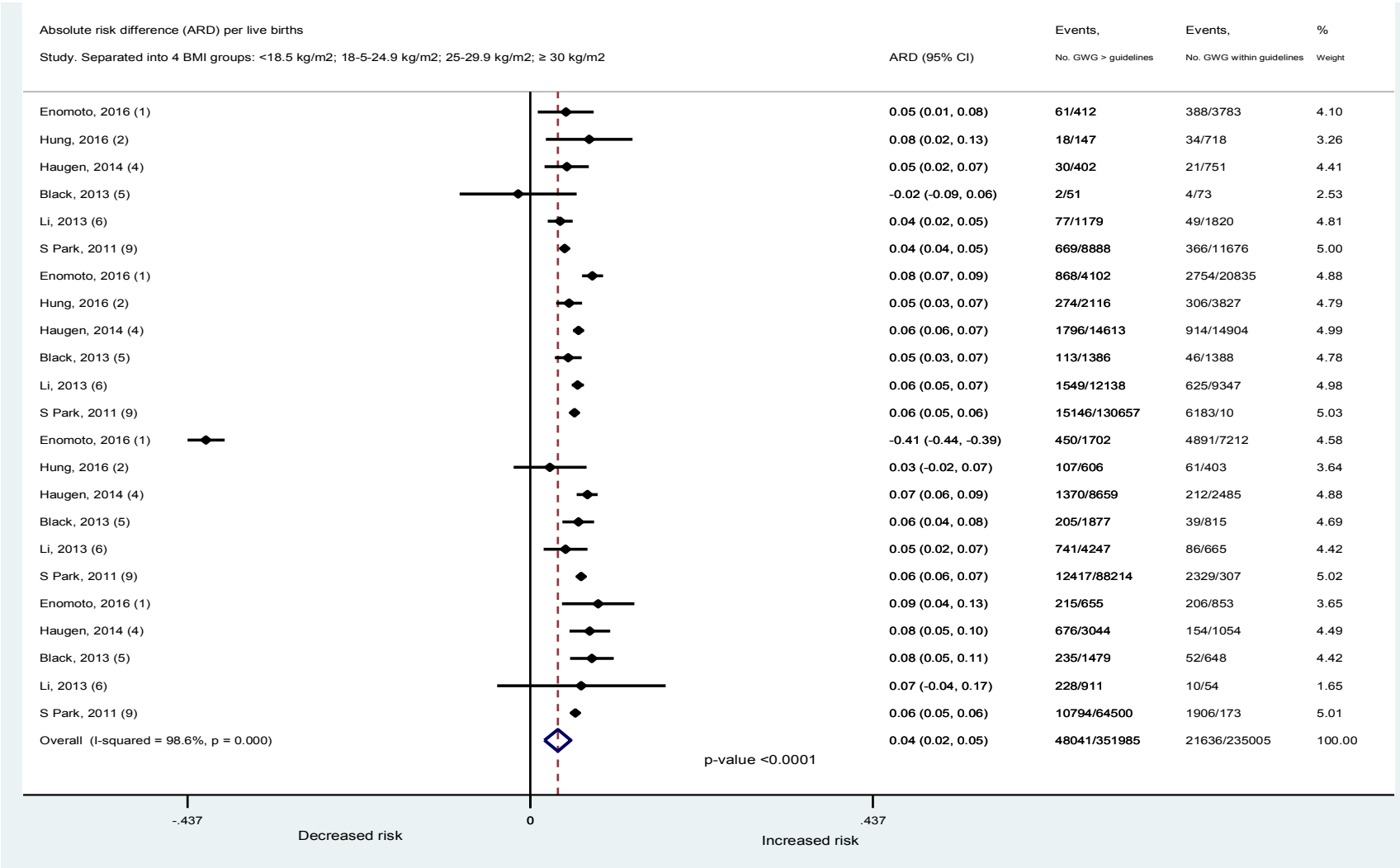
eFigure 2d. Preterm birth: GWG above guidelines (all BMI groups combined)



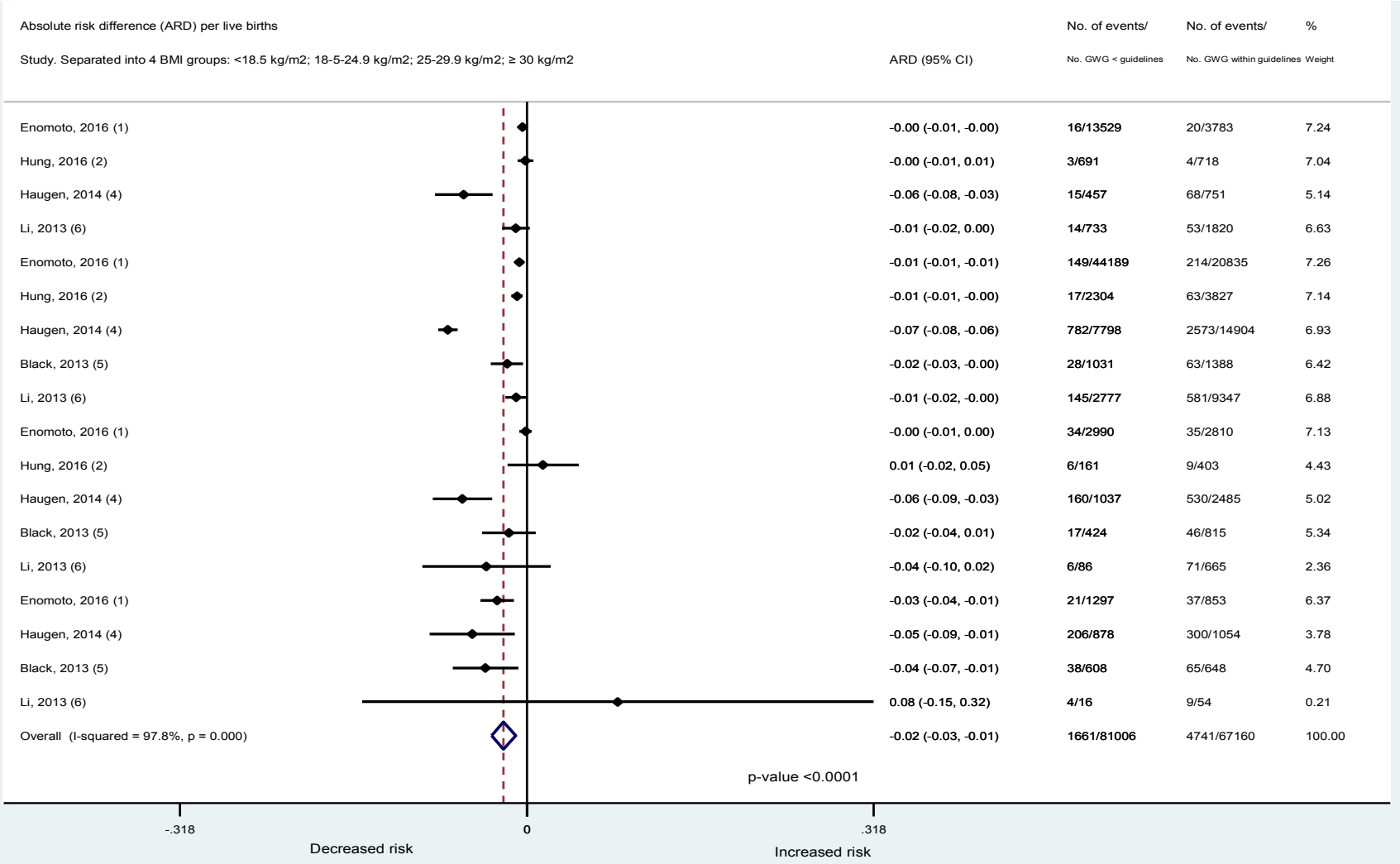
eFigure 2e. Large for gestational age (LGA): GWG below guidelines (all BMI groups combined)



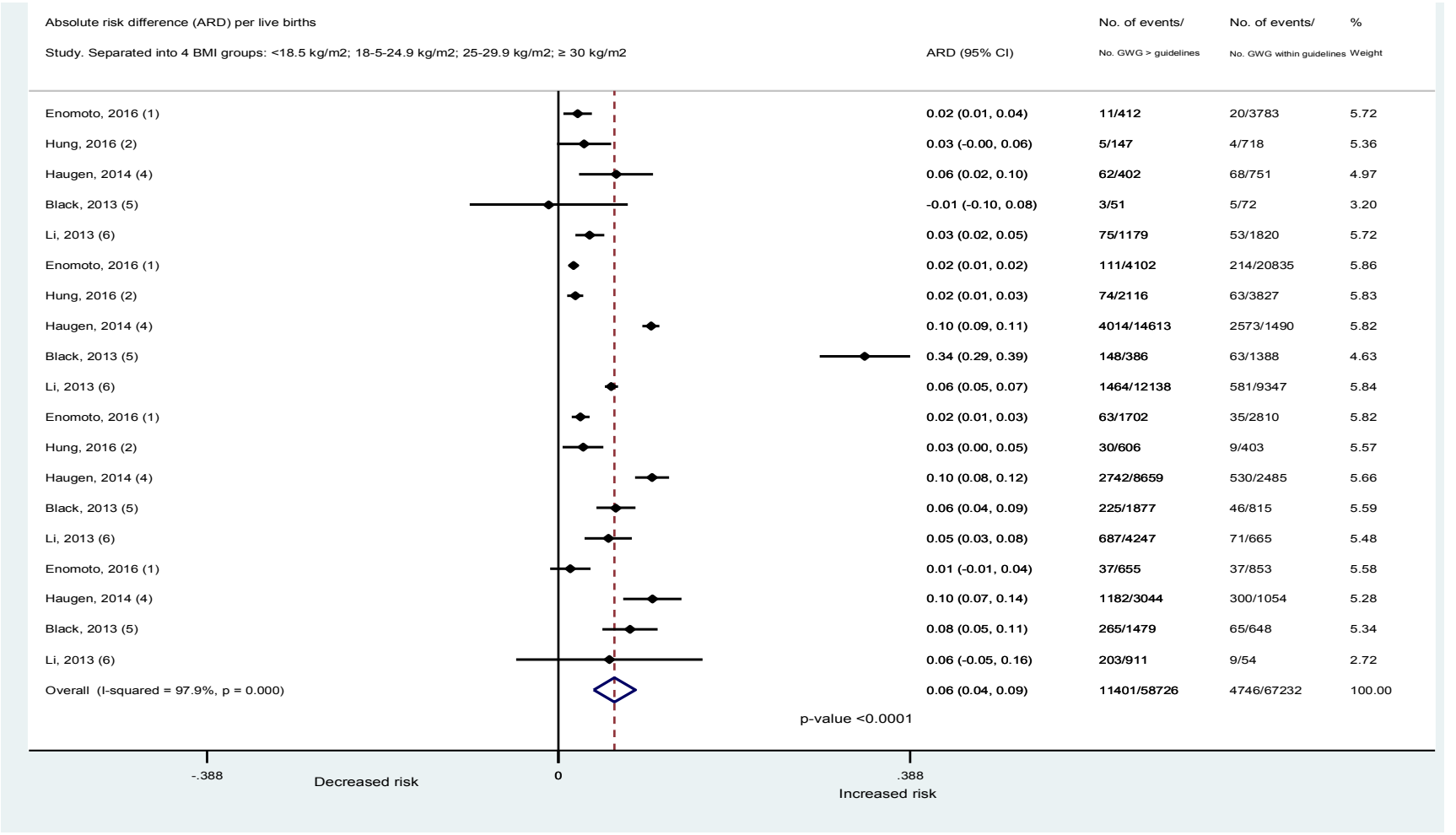
eFigure 2f. Large for gestational age (LGA): above guidelines (all BMI groups combined)



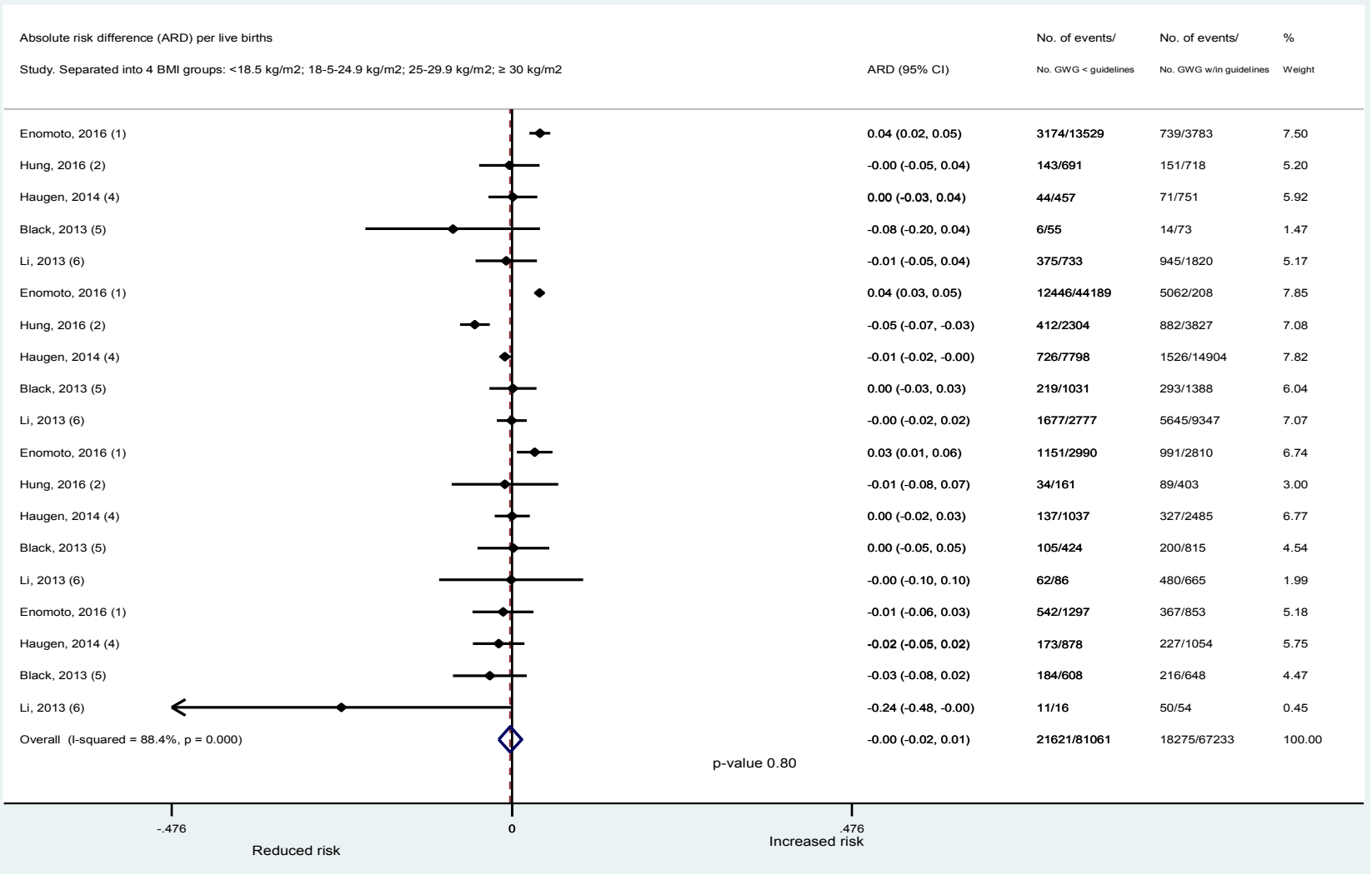
eFigure 2g. Macrosomia: below guidelines (all BMI groups combined)



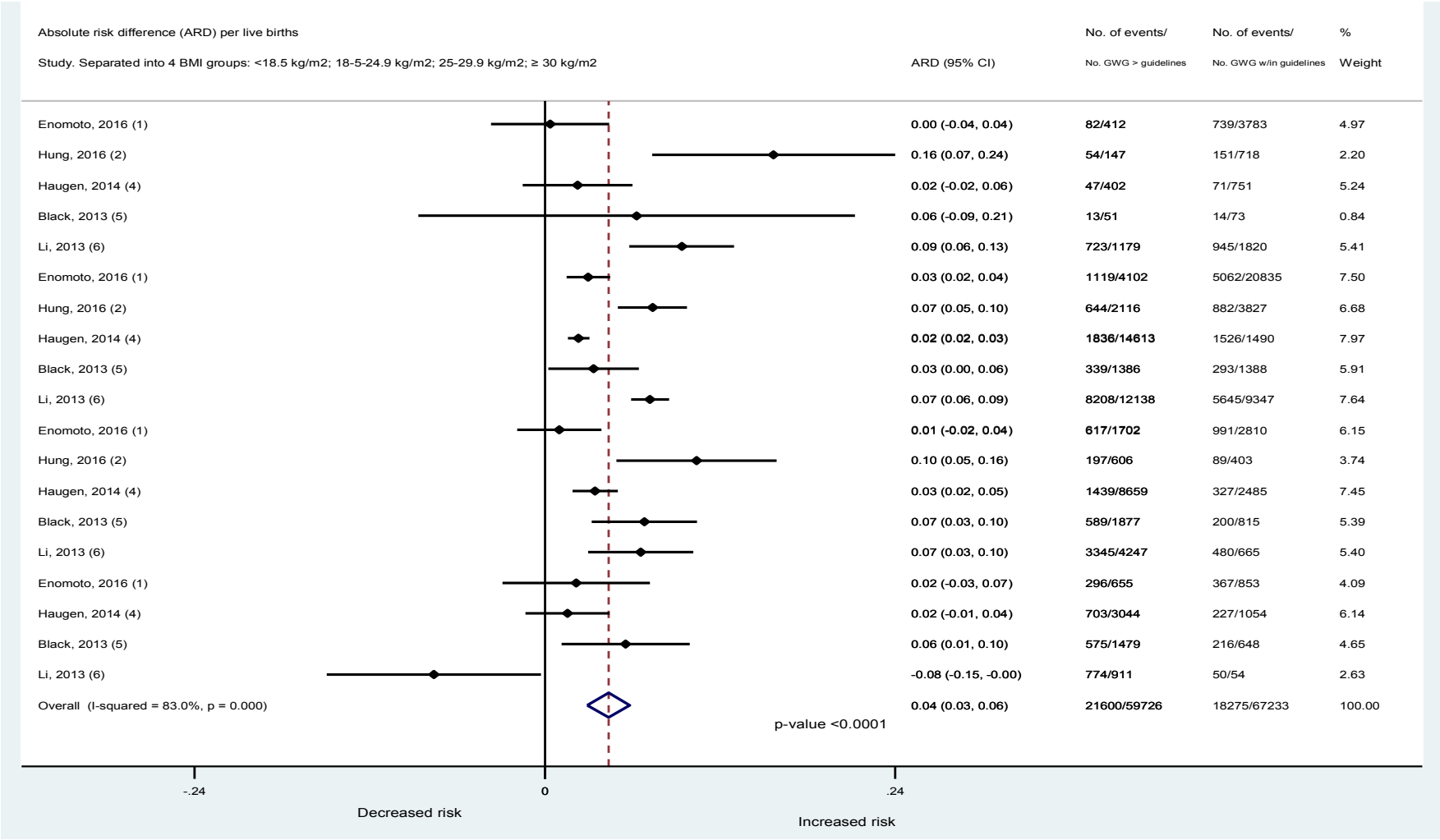
eFigure 2h. Macrosomia: above guidelines (all BMI groups combined)



eFigure 2i. Caesarean: below guidelines (all BMI groups combined)



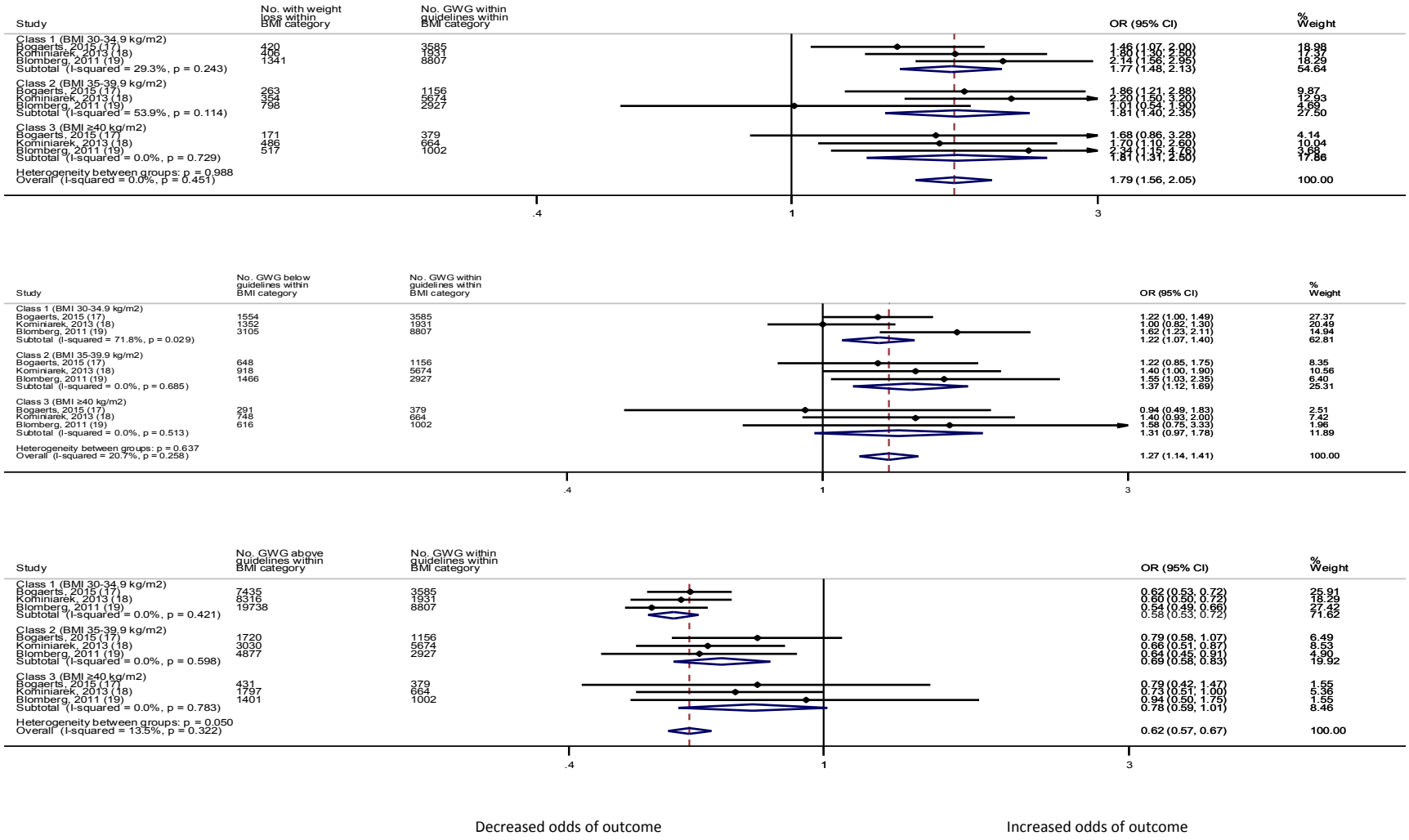
eFigure 2j. Caesarean: above guidelines (all BMI groups combined)



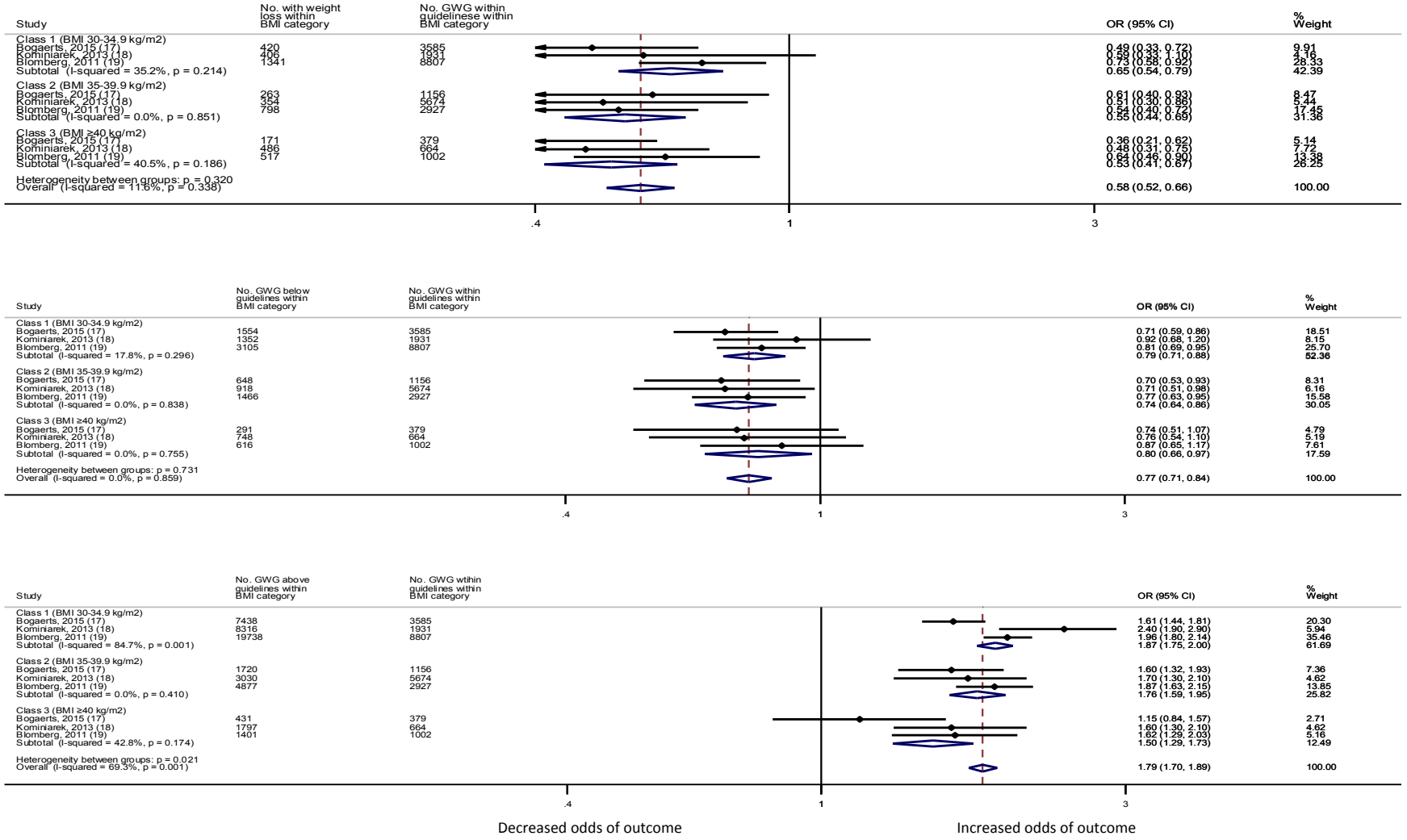
eFigure 3. Pooled OR for Primary and Secondary Outcomes for Obese Subgroup

Reference group = women with recommended weight gain in each BMI group

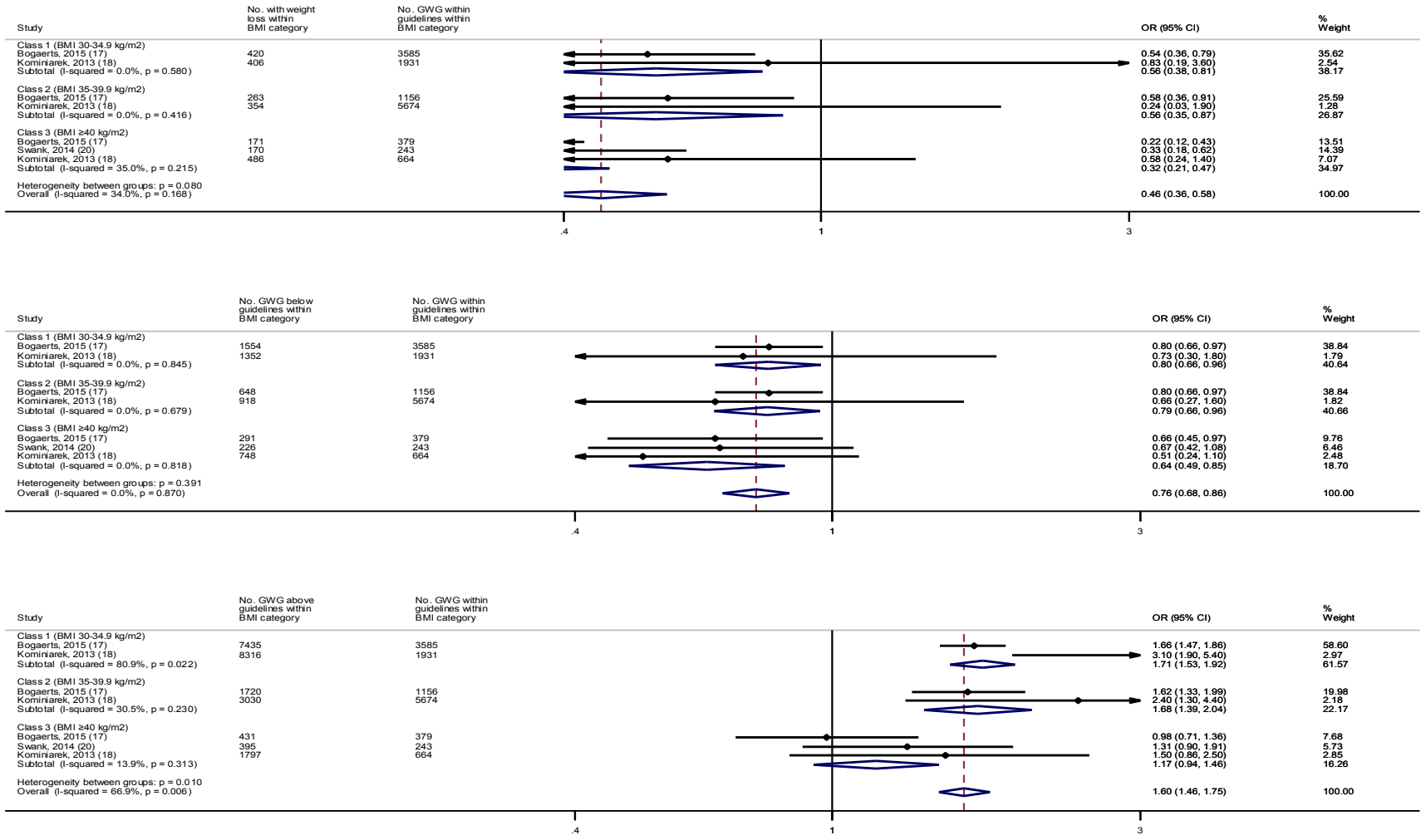
eFigure 3a. Small for gestational age (SGA)



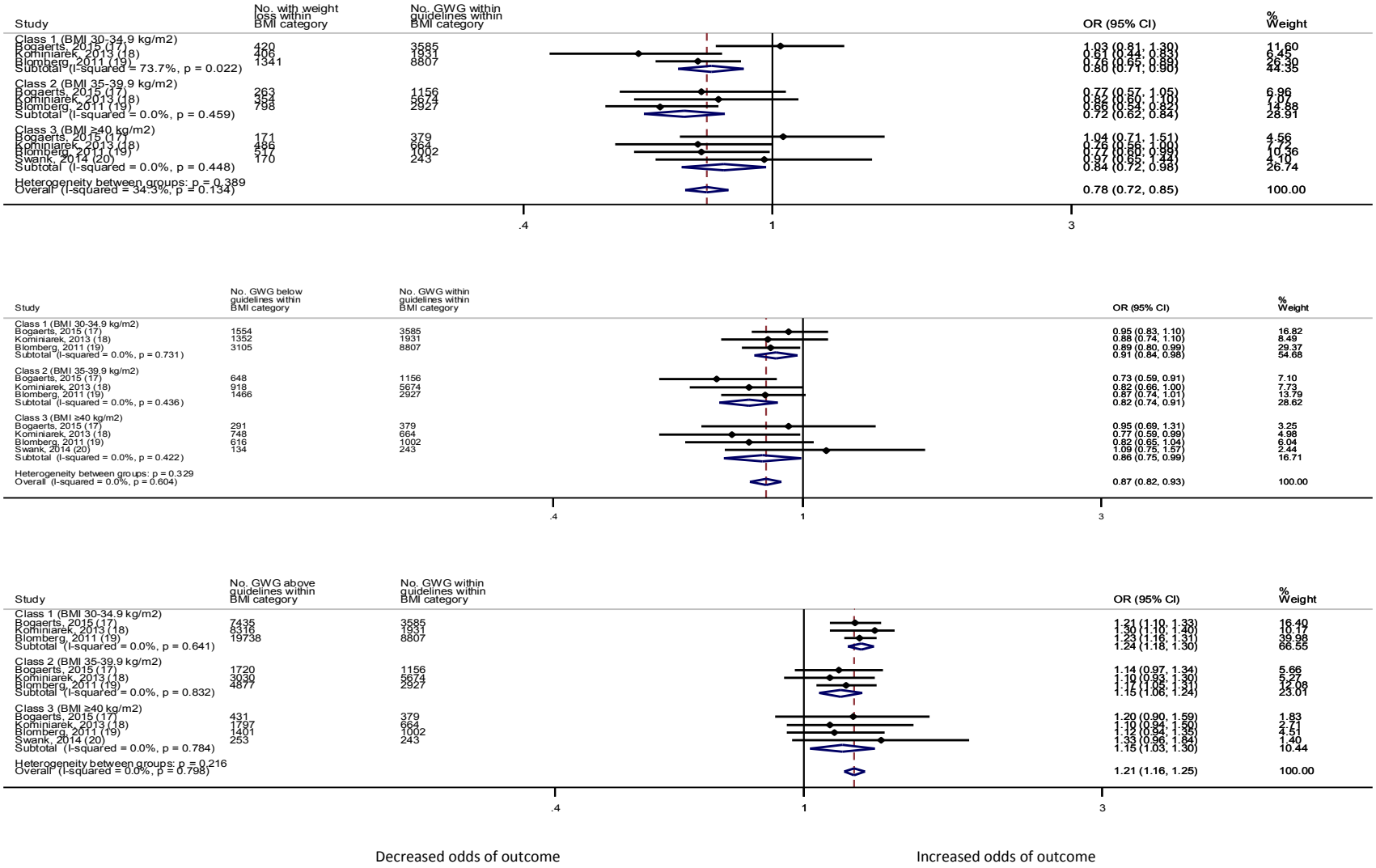
eFigure 3b. Large for gestational age (LGA)



eFigure 3c. Macrosomia



eFigure 3d. Caesarean section

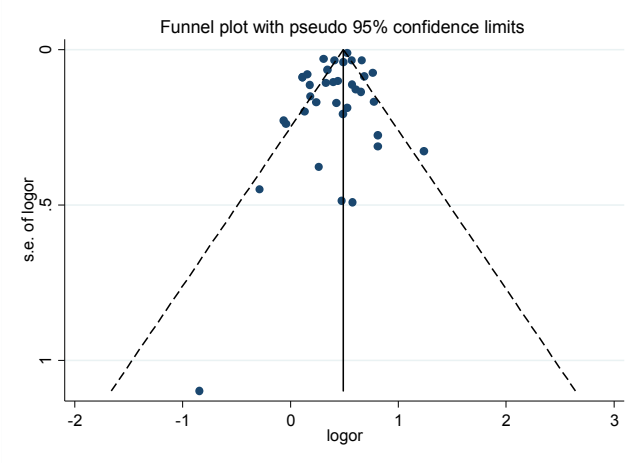


eFigure 4. Publication Bias

eFigure 4a. Small for gestational age (SGA) – GWG below guidelines

Egger's test: p-value 0.11

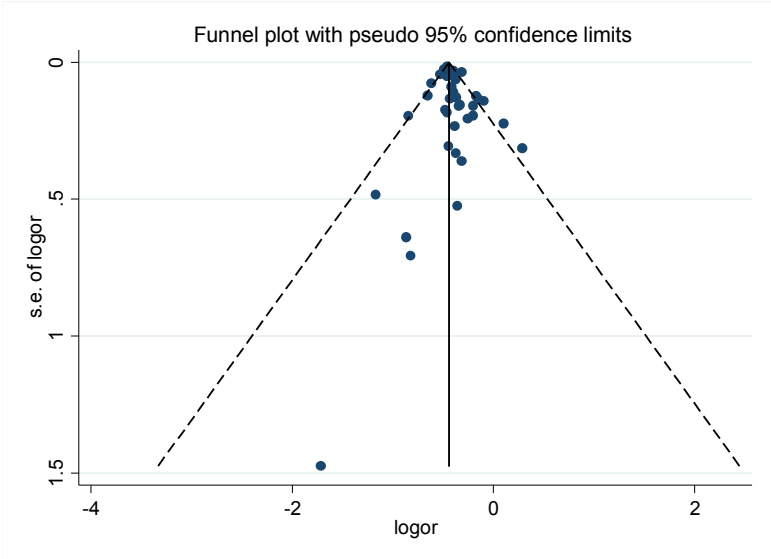
11 studies (36 data points, individual OR from every study for each BMI category)



eFigure 4b. Small for gestational age (SGA)– GWG above guidelines

Egger's test: p-value 0.16

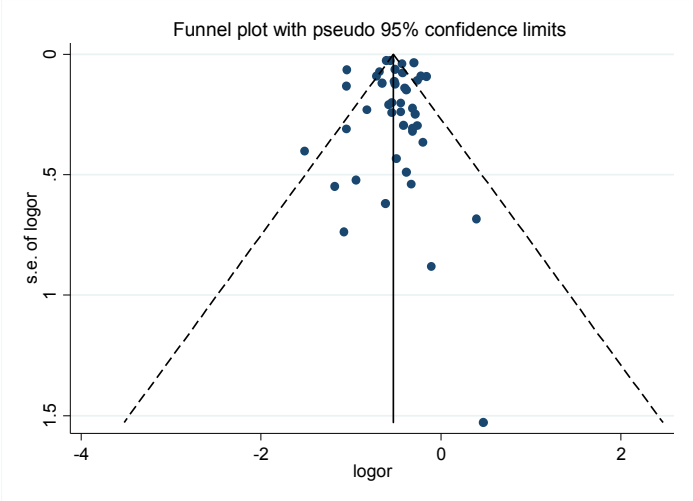
11 studies (37 data points, individual OR from every study for each BMI category)



eFigure 4c. Large for gestational age (LGA) –GWG below guidelines

Egger's test: p-value 0.89

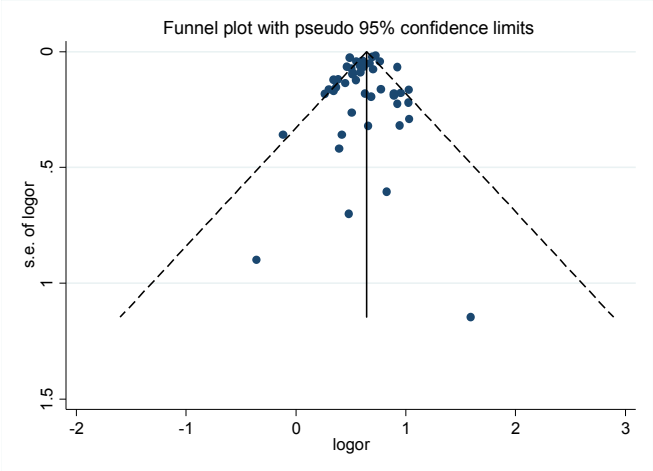
13 studies (43 data points, individual OR from every study for each BMI category)



eFigure 4d. Large for gestational age (LGA) – GWG above guidelines

Egger's test: p-value 0.29

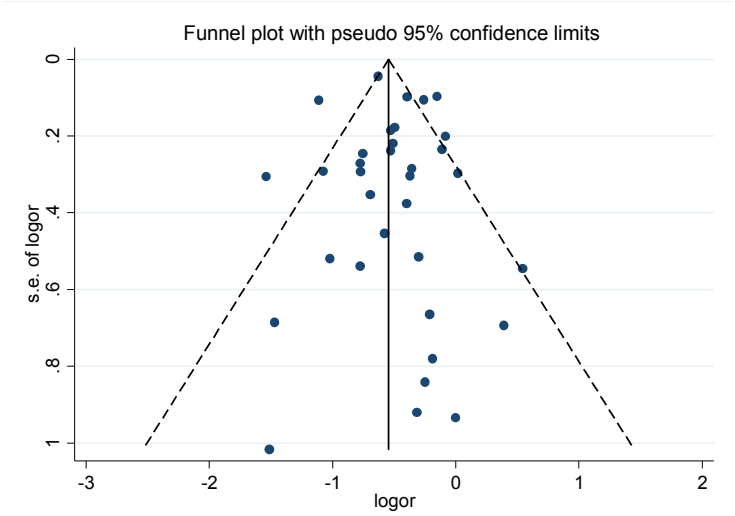
13 studies (44 data points, individual OR from every study for each BMI category)



eFigure 4e. Macrosomia – GWG below guidelines

Egger's test: p-value 0.61

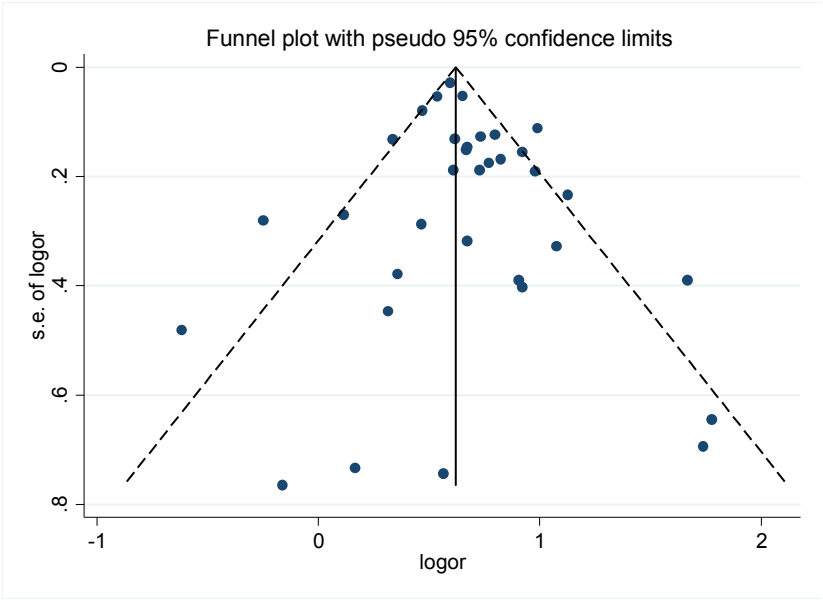
11 studies (34 data points, individual OR from every study for each BMI category)



eFigure 4f. Macrosomia –GWG above guidelines

Egger's test: p-value 0.30

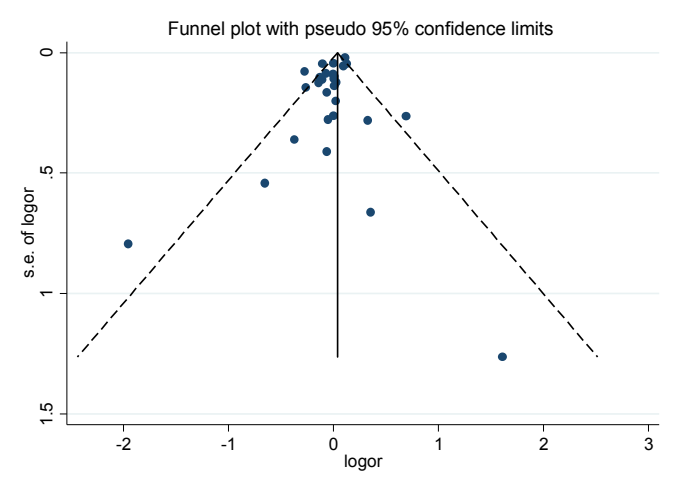
11 studies (34 data points, individual OR from every study for each BMI category)



eFigure 4g. Caesarean section – GWG below guidelines

Egger's test: p-value 0.05

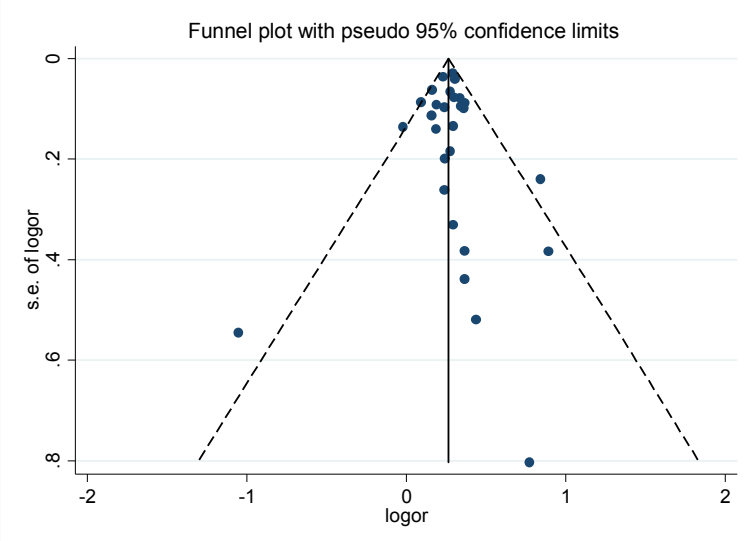
8 studies (28 data points, individual OR from every study for each BMI category)



eFigure 4h. Caesarean section –GWG above guidelines

Egger's test: p-value 0.99

8 studies (28 data points, individual OR from every study for each BMI category)



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Appendix. Supplement to Publication 2.3

Additional files

Gestational Weight Gain Across Continents and Ethnicity: Systematic Review and Meta-Analysis of Maternal and Infant Outcomes in More Than One Million Women.

Goldstein RF, Abell SK, Ranasinha S,et al

BMC Medicine. 2018 Aug 31;16(1):153.

1. Search Terms

2. Additional Methods

3. Table 1. Descriptive characteristics of 23 included studies

4. Table 2. Risk of bias

5. Figure 1**.** Summary of pooled OR for the association between gestational weight gain below and above guidelines for adverse outcomes

6. Figure 2. Subgroup analysis for Asian studies that used regional BMI categories (China, Korea) vs WHO BMI categories (Japan, Taiwan) for the association between gestational weight gain below and above guidelines for adverse outcomes

7. Table 3**.** Body mass index at onset of pregnancy for Asian studies

8. Table 4. Gestational weight gain during pregnancy for Asian studies

9. Table 5. Metaregression

10. Figure 3. Publication bias

Additional file 1: Search terms

Searches	Results
Weight Gain/	23347
Pregnancy/	702831
1 and 2	3146
(weight and gain).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	57991
(weight and change).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	48999
4 or 5	100281
pregnan*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	775673
gestation*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	176589
7 or 8	822868
6 and 9	12406
3 or 10	12406
diabetes, gestational/ or fetal macrosomia/	7179
(gestational and diab*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	11182
gdm.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	2715
Pre-Eclampsia/	24030
pre-eclamp*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	26089
preeclamp*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	12721
Hypertension, Pregnancy-Induced/	1711
(gestational and hypertensi*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	6056
Postpartum Hemorrhage/	4842
(postpartum and hemorrhag*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	6438
(postpartum and haemorrhag*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	1573
obstetric labor, premature/ or premature birth/	18496
(preterm or pre-term).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	44753

(birth or labor or labour or deliver*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	730110
24 and 25	32432
cesarean section/ or extraction, obstetrical/ or vacuum extraction, obstetrical/ or labor, induced/	43512
(cesar* or caesar*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	52780
(induc* or instrument* or vacuum).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	2460462
25 and 29	95638
exp Resuscitation/	74306
exp thromboembolism/ or exp thrombosis/	142278
Intensive Care Units/	36416
Pregnancy/	702831
31 or 32 or 33	247846
34 and 35	8272
(resusc* or thrombo* or intensive care or (high and depend*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	763789
pregnan*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	775673
37 and 38	30807
failed instrumental delivery.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	17
Episiotomy/	1709
episiotomy.mp.	2330
anal sphincter injury.mp.	162
(third or fourth).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	379406
degree tears.mp.	120
44 and 45	103
12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 26 or 27 or 28 or 30 or 36 or 39 or 40 or 41 or 42 or 43 or 46	236364
exp Infant, Low Birth Weight/	26757
low birth weight.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	30133
small for gestational age.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	8085
exp Birth Weight/	34313
large for gestational age.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	1111
Congenital Hyperinsulinism/	303

((hypoglycem* or hypoglycaem*) and neonat*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	3013
Fetal Death/	22997
Respiratory Distress Syndrome, Newborn/	11479
(fet* or foet* or neonat*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	548601
(respiratory distress or death or intensive care).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	660039
57 and 58	74044
Intensive Care Units, Neonatal/	9922
shoulder dystocia.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	932
perinatal complication.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	46
birth trauma.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	838
umbilical cord ph.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	118
neonatal adiposity.mp.	38
48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 59 or 60 or 61 or 62 or 63 or 64 or 65	134946
47 or 66	331748
11 and 67	6168
limit 68 to (english language and female and humans and yr="1999 -Current")	2726

Additional file 2. Additional Methods

Screening of search results

A trained clinician reviewer (RG) scanned the titles, abstract sections and keywords of every record retrieved by the search strategy in consultation with a highly experienced systematic reviewer (MM). Studies were selected and appraised by the reviewer in consultation with MM and clinical colleagues with evidence synthesis experience (HT) using study selection and appraisal criteria established *a priori*. Full articles were retrieved for all papers that met initial inclusion criteria, or if clarification was required beyond the abstract. In cases where selection was not clear, a second trained clinician reviewer appraised the paper (SA). Any discrepancies between the two appraisers was discussed with a third review author (MM).

Data extraction

Data were extracted from included studies using a specially developed data extraction form by two reviewers (RG, SA). Information collected included: type of study, study setting, study population, inclusion/exclusion criteria, outcomes measured and confounding factors. Missing data was obtained from the authors wherever possible. Any disagreement was resolved by discussion with an experienced biostatistician to reach a consensus (SR).

Data reanalysis request

Given the wide variation in classification of prepregnancy BMI categories and GWG categories, meaningful interpretation and meta-analysis was not possible. We therefore decided *a priori* to contact these authors to reanalyse and present data in a consistent, homogeneous format. For example, authors were requested to reclassify 1990 IOM GWG categories according to 2009 categories for data synthesis. If multiple weight gain groups within each BMI category were presented, authors were requested to reanalyse their data using 2009 categories.

Thirty one authors were contacted for data reanalysis and additional information, including the proportion of nulliparous women, proportion smoking in pregnancy, and mean maternal age for the meta-regression. This process involved email contact from the lead systematic review authors to the past senior study authors. Legal agreements for data sharing were prepared as well as authorship agreements where substantial reanalysis was required. Thirteen authors provided additional information and were included; eighteen did not provide this, of these three studies were still able to be included. Authors that were unable to reanalyse 1990 IOM data or correct multiple weight gain groups were excluded.

Additional file 3. Table 1. Descriptive characteristics of 23 included studies

Study, year, country	Study period	Study design, sample size	Setting	Inclusion criteria	Exclusion criteria	Confounders in original analysis	Provided additional data or reanalysis	Data for meta-analysis:
Durst, 2016 US	2000-2014	Retrospective 5651	University of Alabama, Birmingham	obese women; those delivering after 36 weeks gestation with documented weight in first trimester and within 10 days before delivery	NR	prior caesarean, age, race, parity, gestational age, payor status, tobacco use	no	Adjusted
Enomoto, 2016 Japan	2013	Retrospective 97157	Japan Society of Obstetrics and Gynecology Registry system with 280 participating hospitals	singleton pregnancy, successful delivery occurring at gestational week 22 or later	women with hypertension of diabetes, history of cervical conization, who delivered a newborn with congenital anomalies, missing data	maternal age, height, parity and additional adjusting for clustering of deliveries by hospitals	no	Adjusted
Hung, 2016 Taiwan	2009-2015	Retrospective 10973	Taipei Chang Gung Memorial Hospital	singleton pregnancy after 37 weeks gestation (cohort 2)	women with pregestational diabetes and hypertension, multiple gestations, fetal chromosomal or structural anomalies, fetal demise	maternal age, parity, prior fetal death, prior preterm birth, conception methods, genetic amniocentesis, smoking in pregnancy, group B strep colonization, fetal sex, epidural	no	Adjusted
Xiong[c], 2016 China	2012-2013	Prospective 57891	Hospitals and community centres	singleton, live-born, term pregnancies	women with diabetes, hypertension, heart disease before or during pregnancy or those with missing height and weight data, women who delivered a stillborn infant or infant with birth defects	maternal age, education, parity, fetal sex, birth weight	no	Adjusted

Table 1. Descriptive characteristics of 23 included studies (continued)

Study, year, country	Study period	Study design, sample size	Setting	Inclusion criteria	Exclusion criteria	Confounders in original analysis	Provided additional data or reanalysis	Data for meta-analysis:
Bogaerts, 2015 Belgium	2009-2011	Retrospective 18053	Flemish study center for perinatal epidemiology	singleton, live births	GW loss >45 kg, GWG > 60kg, extreme prepregnancy weight/height and weight at delivery	parity, maternal age, gestational age	yes	crude
Shin, 2015 US	2004-2011	Retrospective 219868	Pregnancy risk assessment monitoring system (PRAMS)	live births	missing prepregnancy BMI, GWG, preexisting DM and outcomes	maternal age, race, education, income, gestational age, WIC participation, smoking	yes	crude
Wen[e], 2015 China	2009-2013	Retrospective 13776	Jishuitan Hospital	singleton, age 18-40, normal prepregnancy BMI, GWG ≤ 16kg, primipara	GWG > 16kg, any DM, HT, severe congenital anomalies, missing data on BMI, GWG, birth weight or pregnancy outcomes	income, maternal education, occupation, weight gain advice, residential area	no	adjusted
Yang[e], 2015 China	2011-2013	Prospective 85765	Wuah Women and Children Health Care Center	singleton, live birth, gestational age ≥ 28 wk	NR	maternal age, maternal education, infant gender (provided crude and adjusted)	no	crude
Badon, 2014 US	2000-2006	Prospective 5297	North American Field Centers, HAPO	pregnant women < 31 weeks gestation	age < 18, multiple pregnancy, previous diabetes, diabetes in pregnancy	gender, race, parity, study centre, maternal age, OGTT z score sum, alcohol use, smoking, family history of diabetes, hospitalisation pre delivery gestational age at last prenatal weight and OGTT mean arterial pressure at OGTT, maternal height	no	adjusted
Chihara, 2014 US	2003-2005	Retrospective 19130	Hawaii's special supplemental program for women, infants and children (WIC)	NR	no prenatal record, gestational age <20 or >44 wk, multiple births, missing GWG, birthweight	maternal age, education, race/ethnicity, marital status, smoking status, parity	no	adjusted

Table 1. Descriptive characteristics of 23 included studies (continued)

Study, year, country	Study period	Study design, sample size	Setting	Inclusion criteria	Exclusion criteria	Confounders in original analysis	Provided additional data or reanalysis	Data for meta-analysis:
Haugen[c], 2014 Norway	1999-2008	Prospective 56082	Norwegian Mother and Child cohort study	prepregnancy weight and height, weight at delivery and 6 months post partum	gestation < 37 or > 42 wk, GWG < -30kg or > 50kg, age < 18 years, women with 2nd or 3rd participation in study	maternal age, maternal height, maternal education, gestational length, smoking, diabetes	yes	Crude
Lee[d], 2014 Korea	2010-2012	Retrospective 16297	Single medical centre	singleton, live births	pre-existing medical conditions (diabetes and HT)	maternal age, parity	yes	crude
Swank, 2014 US	2007	Retrospective 1034	Californian birth certificate data	singleton, live birth, gestation 24-42 (+6) wk	unknown prepregnancy BMI	maternal age, parity, race, hypertension, pregestational diabetes	yes	crude
Black, 2013 US	2005-2010	Retrospective 9835	Kaiser Permanente Southern California	singleton, live birth gestation ≥ 20 wk	those requiring treatment for GDM	maternal age, race/ethnicity, parity, infant sex, presence of PE/E	yes	crude
Kominiarek[b], 2013 US	2002-2008	Retrospective 21020	12 institutions (19 hospitals)	BMI ≥ 30 kg/m², singleton, live birth, ≥ 37 wk, known GWG	weight loss > 20kg, weight gain > 50kg	age, race/ethnicity, marital status, insurance, parity, smoking, gestational age	yes	adjusted
Li[a], 2013 China	2009-2011	Retrospective 33973	Tianjin Women and Children's Health Center	mother-child pairs with information and clinical measurements	multiple births, stillbirths, multiparous women, missing variables	maternal age, maternal height, maternal education, smoking, family income, maternal occupation, gestational age	yes	crude
Di Benedetto, 2012 Italy	2004-2009	Retrospective 2225	University Hospital	Caucasian women, had glucose challenge test	gestation < 37 weeks, twin pregnancy, glucose intolerance in pregnacy, missing delivery information	gestational age at delivery, glycaemia	yes	crude
Moore Simas, 2012 US	2006-2010	Retrospective 11203	University Hospital	singleton, live birth	congenital anomaly, missing prepregnancy weight, height, GWG, unknown neonate gender or weight, gestation < 22 wk or > 44 wk	both crude and adjusted. marital status, race, parity, smoking, diabetes, hypertension	yes	crude

Table 1. Descriptive characteristics of 23 included studies (continued)

Study, year, country	Study period	Study design, sample size	Setting	Inclusion criteria	Exclusion criteria	Confounders in original analysis	Provided additional data or reanalysis	Data for meta-analysis:
Blomberg, 2011 Sweden	1993-2008	Retrospective 46595	Swedish Medical birth registry	BMI ≥ 30 kg/m², singleton, live birth, ≥ 37 wk	extreme GWG or GW loss	maternal age, parity, smoking	no	adjusted
J Park[d] 2011 Korea	2005-2007	Retrospective 2311	University Hospital	live births, gestation 28-42 weeks	missing prepregnancy BMI, hypertension, diabetes, twin pregnancy, congenital anomaly, previous caesarean	both crude and adjusted. BMI, smoking, parity, education, husbnad's education, gestational age, gestational diabetes	yes	crude
S Park, 2011 US	2004-2007	Retrospective 560672	Florida birth certificate data	singleton, live birth, gestational 37-41 wk, age 18-40 years	chronic diabetes, chronic hypertension, missing information for BMI, GWG, LGA or SGA status	maternal age, parity, gestational age, education, smoking, WIC program participation, total number of prenatal visits, infant sex, infant birth year	yes	crude
Vesco, 2011 US	2000-2005	Retrospective 2080	Kaiser Permanente group practice	prepregnancy weight, delivery weight, height	diabetes (gestational and pregestational), hypertension	age, BMI, gestation, race, parity smoking, Medicaid (provided crude and adjusted)	no	crude
Rode, 2007 Denmark	1996-1998	Prospective 2248	University Hospital	age > 18 years, Danish speaking, no alcohol or drug abuse, completed both questionnaires	multiple gestations, gestational age < 37 weeks, missing infant birth weight	smoking status	yes	crude

Key

a	data according to both Chinese and WHO BMI categories (Chinese reported here)
b	sample size changed when provided additional data, OR not recalculated
c	sample size changed when provided additional data
d	data according to both Korean and WHO BMI categories (Korean reported here)
e	data according to Chinese BMI categories
NR	not reported

Additional file 4. Table 2. Summary of risk of bias assessment

Study, year	Selection bias Exposed cohort representative	Detection bias		Reporting bias Free of selective outcome reporting	Assessment of confounding in original analysis	Conflict of interest	Overall risk of bias
		Adequate exposure measures	Adequate outcome measures				
Durst, 2016	yes	yes	yes	yes	yes	no	low
Enomoto, 2016	yes	NR	yes	yes	yes	no	low
Hung, 2016	yes	yes	yes	yes	yes	no	low
Xiong, 2016	yes	yes	yes	yes	yes	no	low
Bogaerts, 2015	yes	yes	yes	yes	yes	no	low
Shin, 2015	yes	yes	no (self reported)	yes	partially (did not adjust for parity)	no	moderate
Wen, 2015	NR	yes	NR	partial (not all outcomes reported)	partially (did not adjust for required number of confounders)	no	moderate
Yang, 2015	yes	yes	yes	yes	yes	no	low
Badon, 2014	yes	yes	yes	yes	yes	no	low
Chihara, 2014	yes	partial (self reported final weight)	no (self reported)	yes	yes	NR	moderate
Haugen, 2014	yes	partial (self reported final weight)	yes	yes	yes	no	low
Lee, 2014	NR	yes	yes	yes	yes	no	low
Swank, 2014	yes	yes	yes	yes	yes	no	low
Black, 2013	yes	yes	yes	yes	yes	no	low
Kominiarek, 2013	yes	yes	yes	yes	yes	no	low
Li, 2013	yes	yes	yes	yes	yes	no	low
Di Benedetto, 2012	yes	yes	yes	yes	partially (did not adjust for parity)	no	low
Moore Simas, 2012	yes	partial (some self reported final weight)	yes	yes	yes	no	low

Table 2. Summary of risk of bias assessment (continued)

Study, year	Selection bias Exposed cohort representative	Detection bias		Reporting bias Free of selective outcome reporting	Assessment of confounding in original analysis	Conflict of interest	Overall risk of bias
		Adequate exposure measures	Adequate outcome measures				
Blomberg, 2011	yes	yes	yes	yes	yes	no	low
J Park, 2011	yes	yes	yes	partial (not all outcomes reported)	yes	NR	low
S Park, 2011	partial	NR	yes	yes	yes	NR	low
Vesco, 2011	yes	yes	yes	yes	yes	no	low
Rode, 2007	NR	partial (self reported final weight)	yes	yes	partially (did not adjust for parity)	NR	low

NR = not reported

Additional file 5. Summary of pooled OR for the association between gestational weight gain below and above guidelines for adverse outcomes

Figure 1a. Small for gestational age (SGA): GWG below guidelines

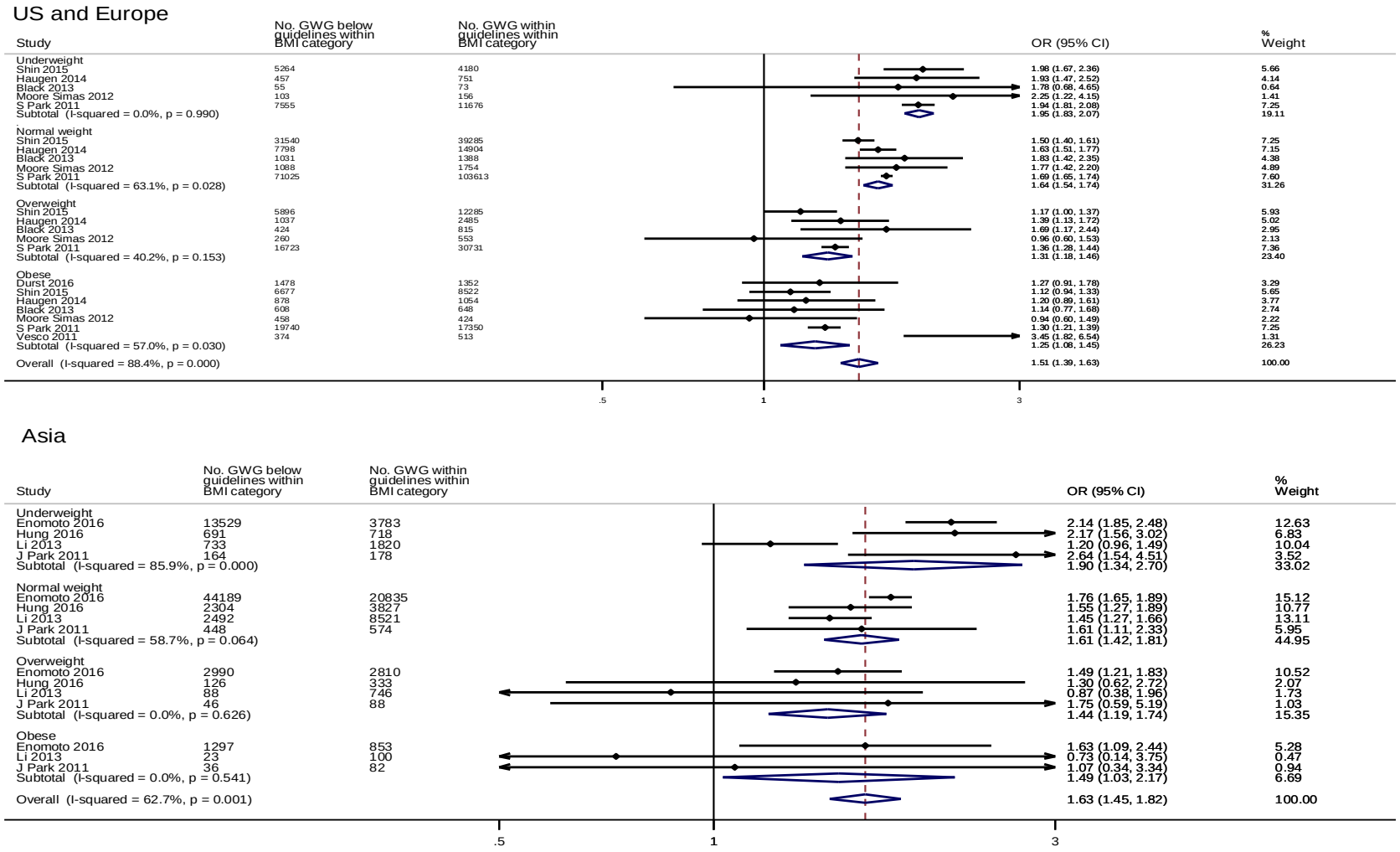
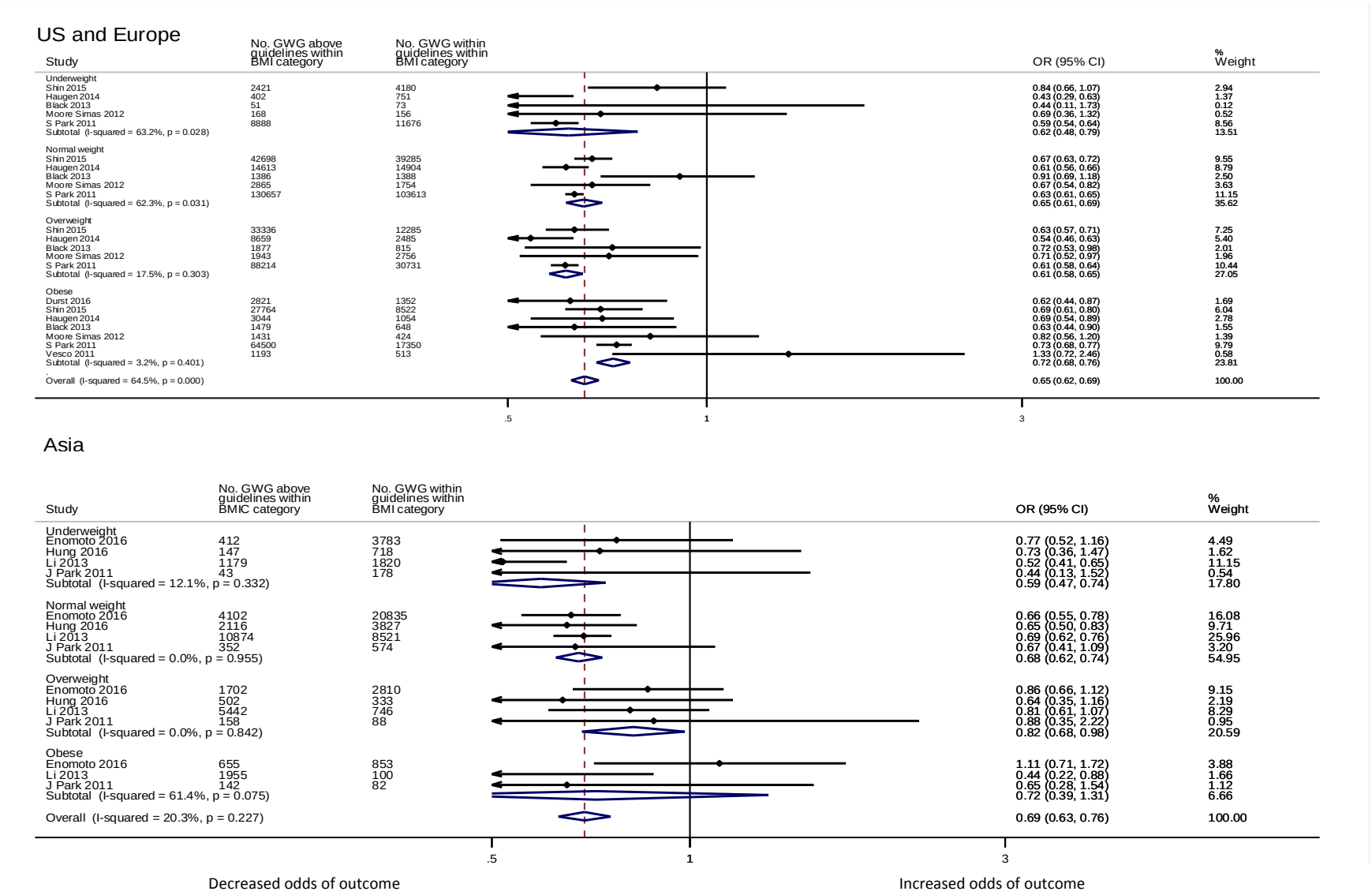
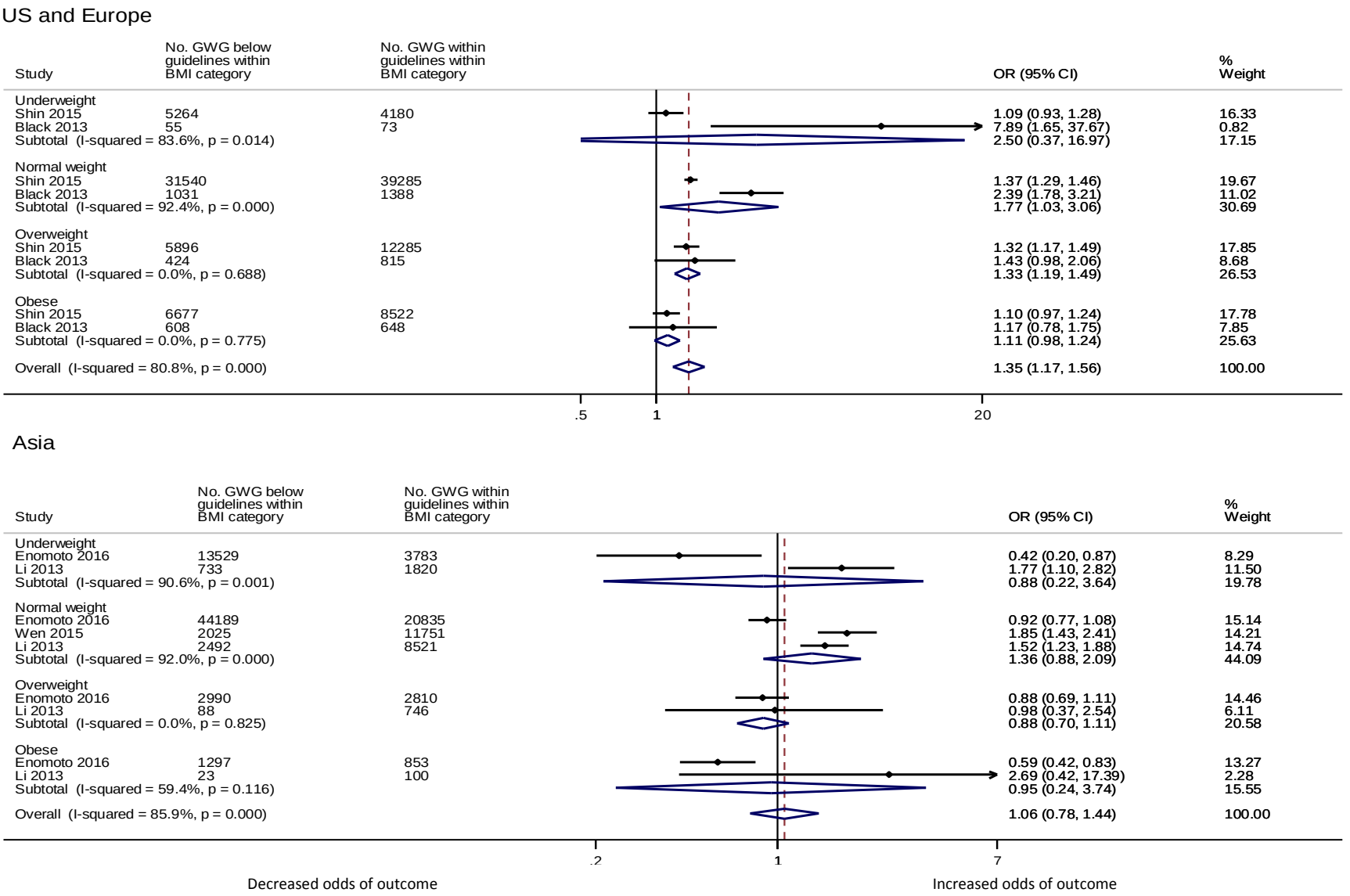


Figure 1b. Small for gestational age (SGA): GWG above guidelines



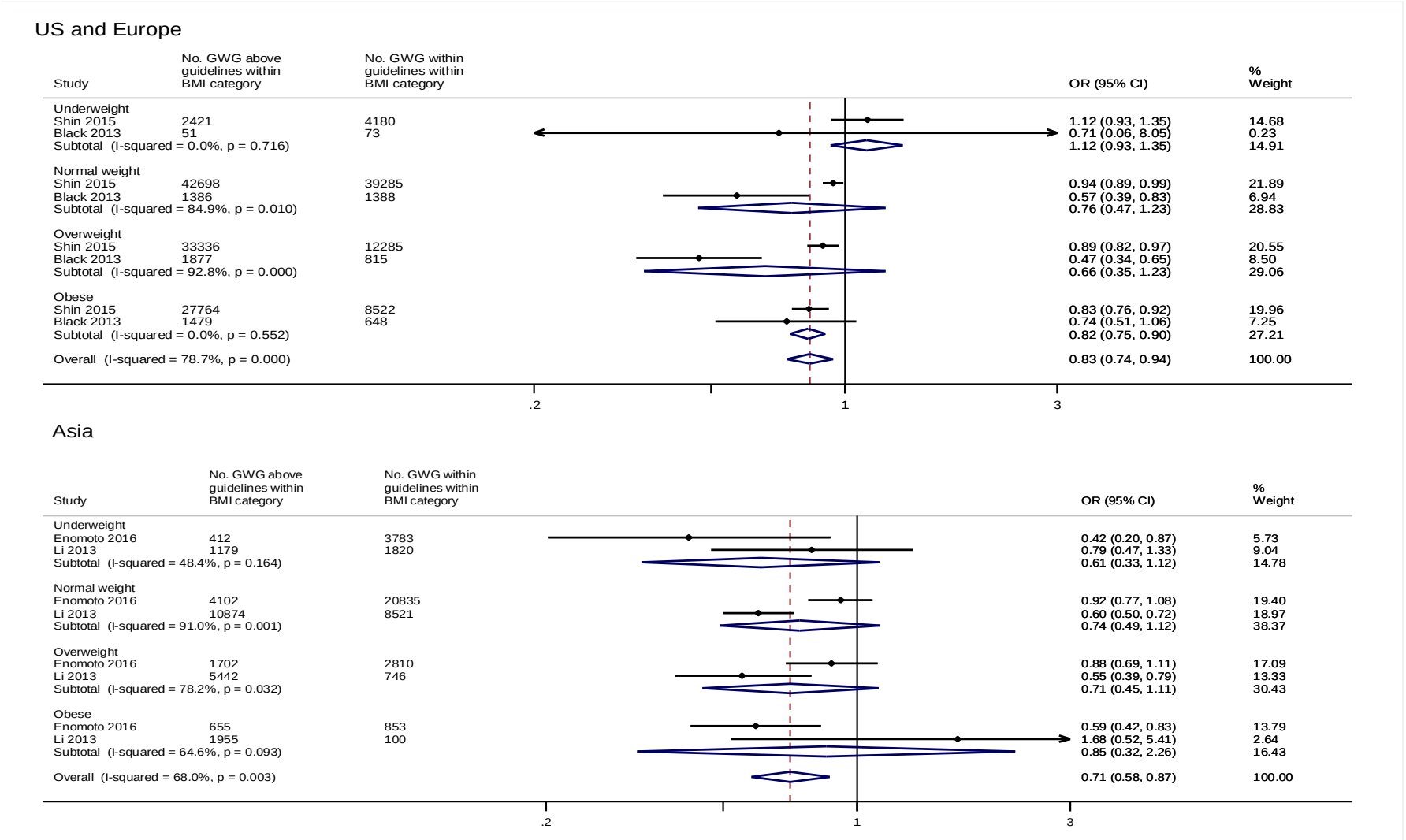
Reference group = women with recommended weight gain in each BMI group

Figure 1c. Preterm birth: GWG below guidelines



Reference group = women with recommended weight gain in each BMI group

Figure 1d. Preterm birth: GWG above guidelines

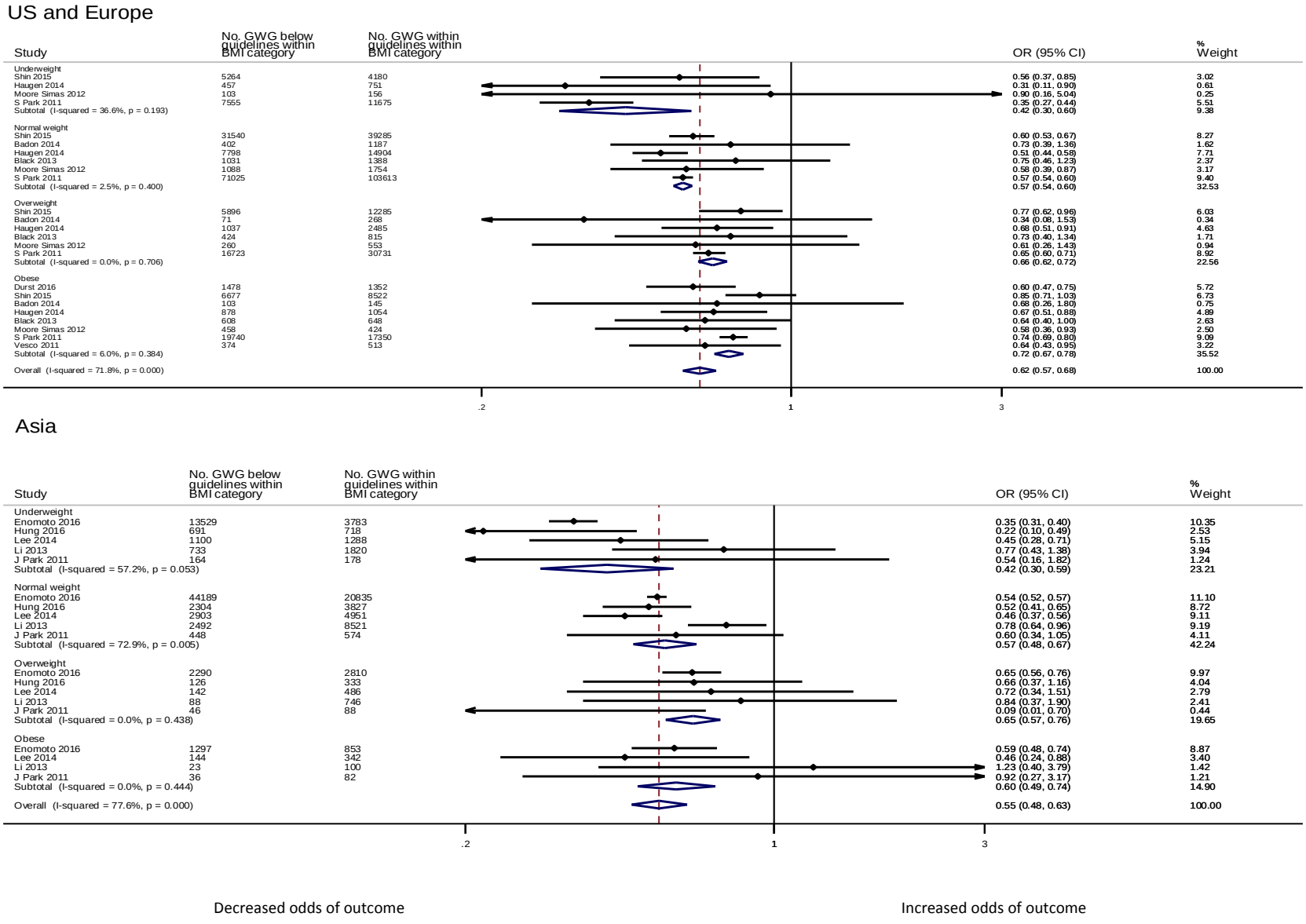


Decreased odds of outcome

Increased odds of outcome

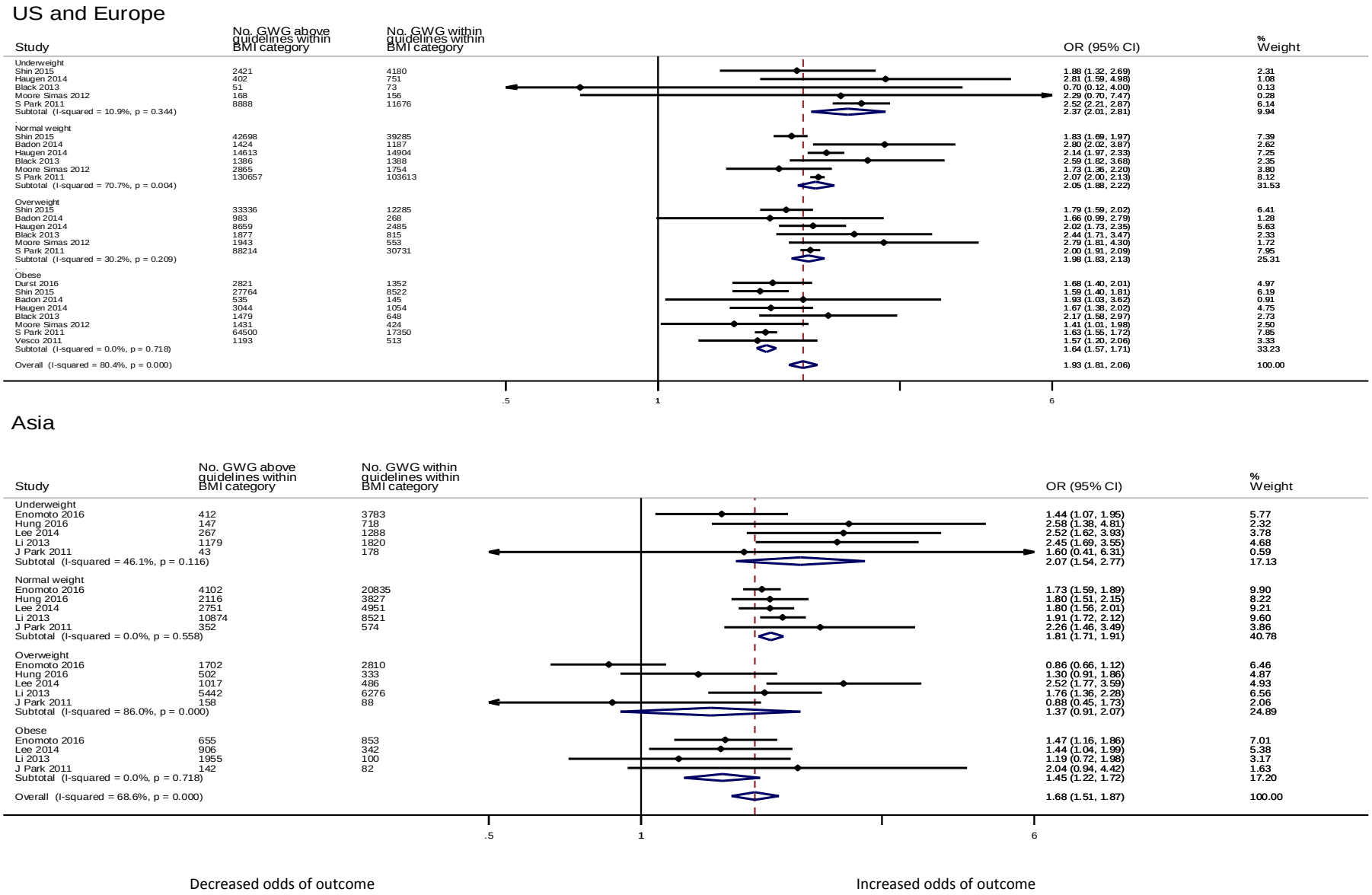
Reference group = women with recommended weight gain in each BMI group

Figure 1e. Large for gestational age (LGA): GWG below guidelines



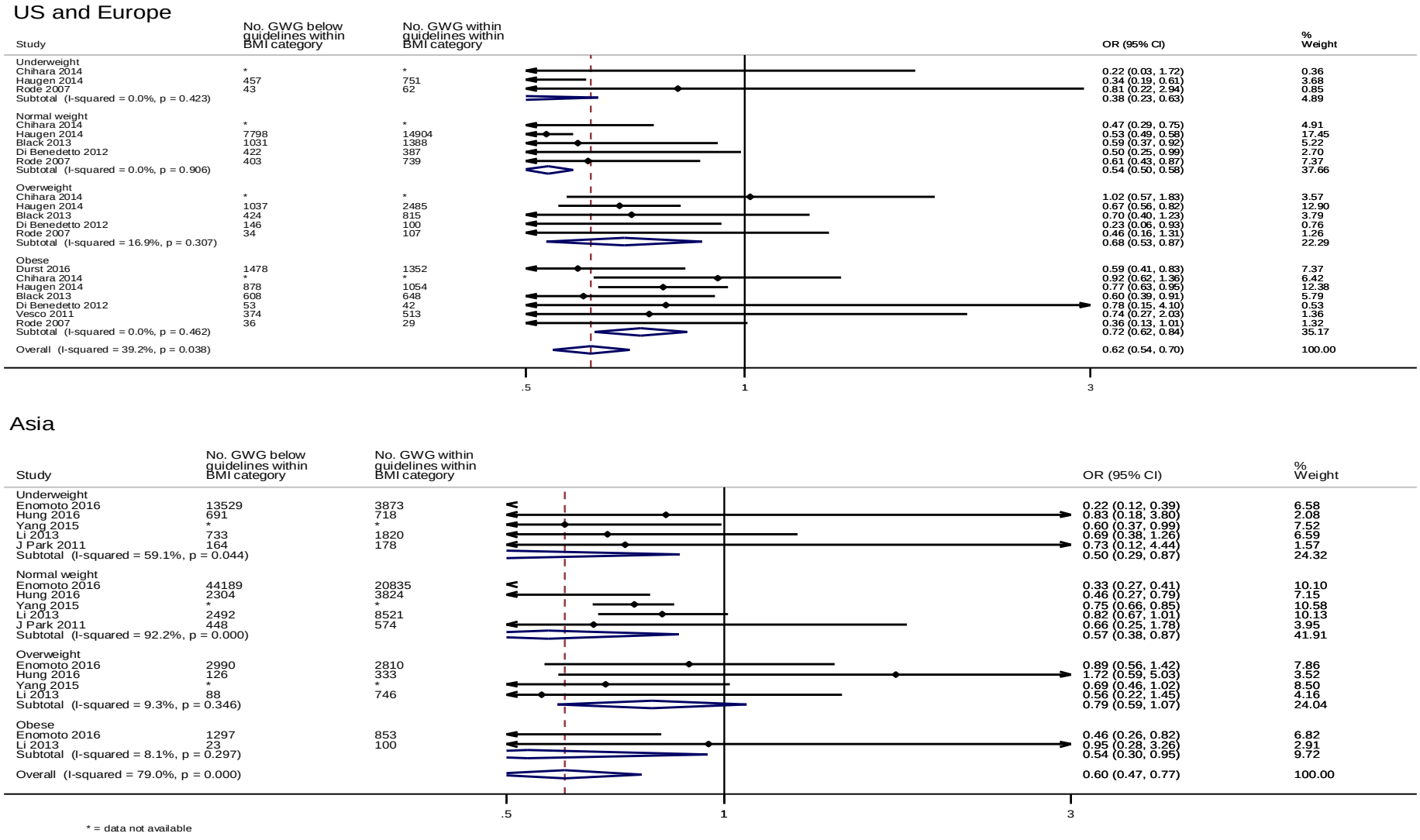
Reference group = women with recommended weight gain in each BMI group

Figure 1f. Large for gestational age (LGA): GWG above guidelines



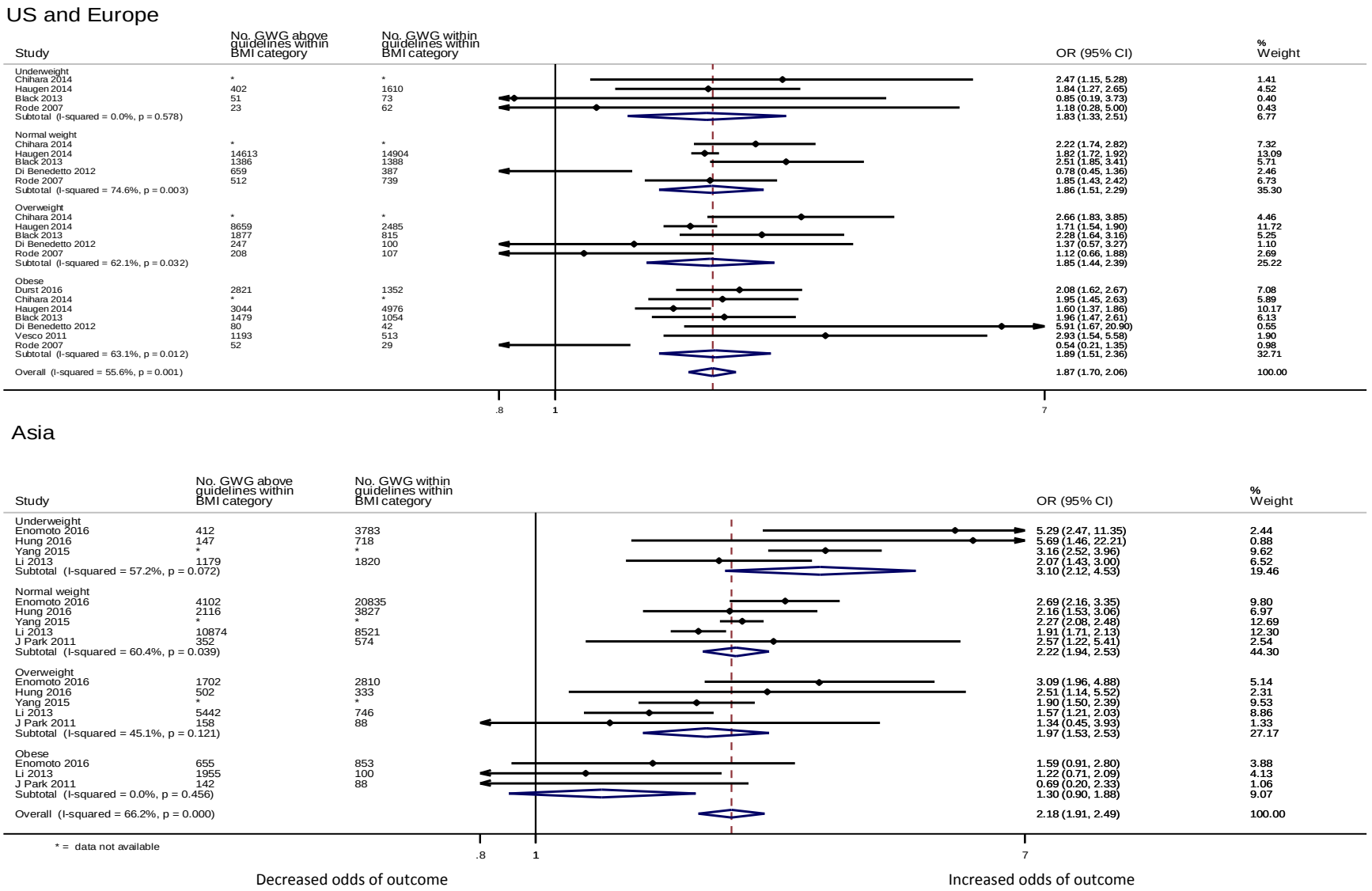
Reference group = women with recommended weight gain in each BMI group

Figure 1g. Macrosomia: GWG below guidelines



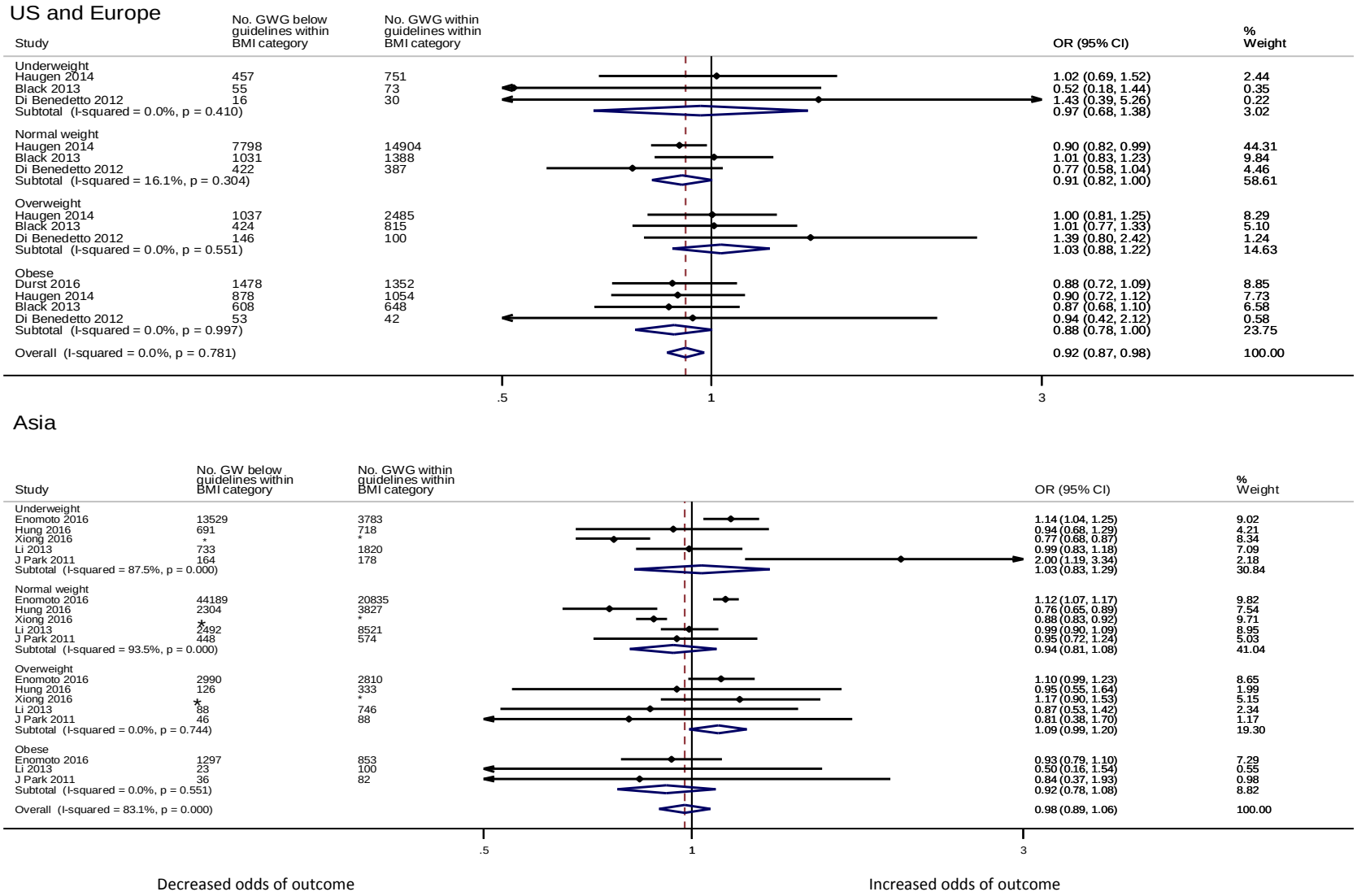
Reference group = women with recommended weight gain in each BMI group

Figure 1h. Macrosomia: GWG above guidelines



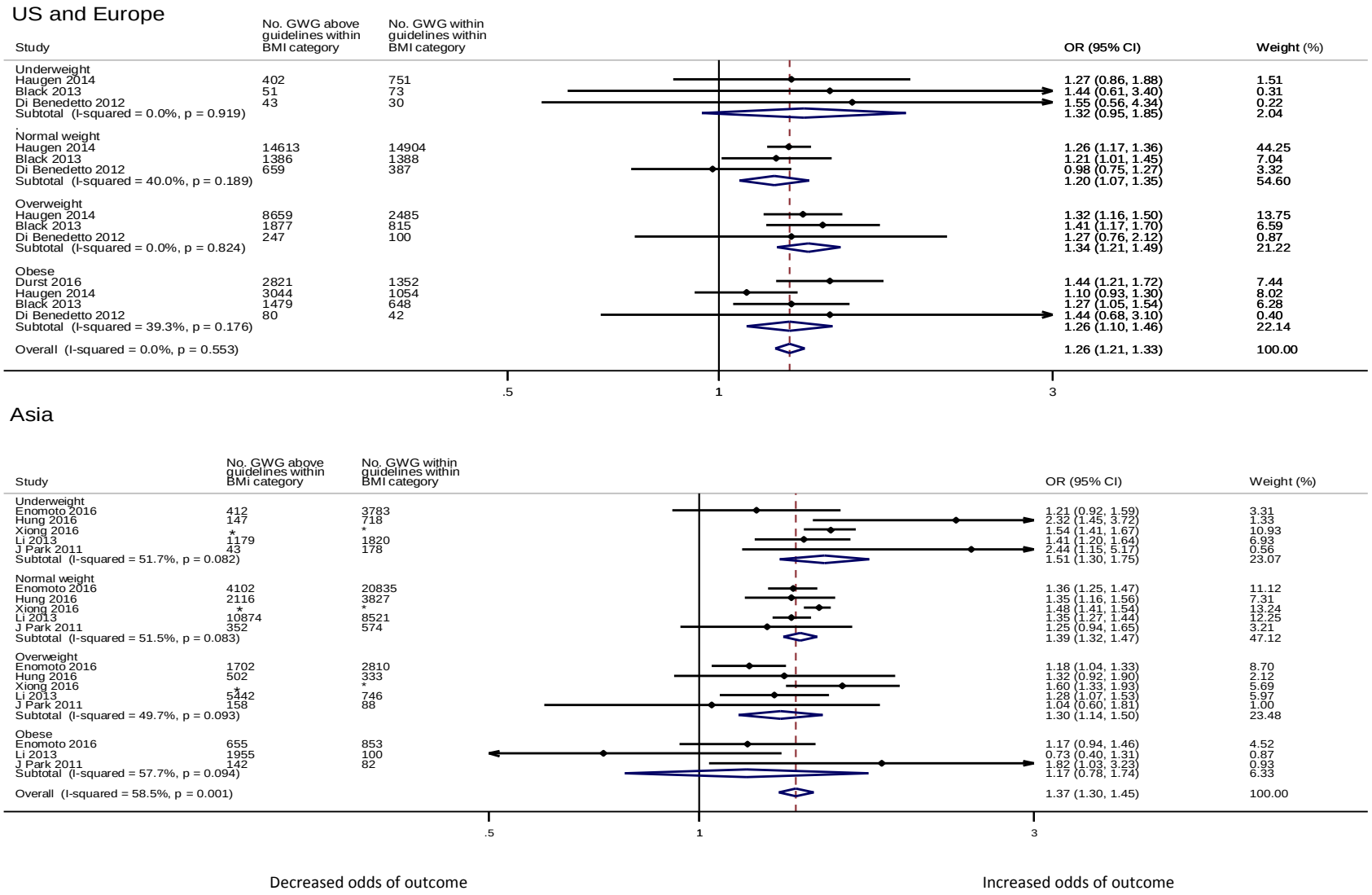
Reference group = women with recommended weight gain in each BMI group

Figure 1i. Caesarean delivery: GWG below guidelines



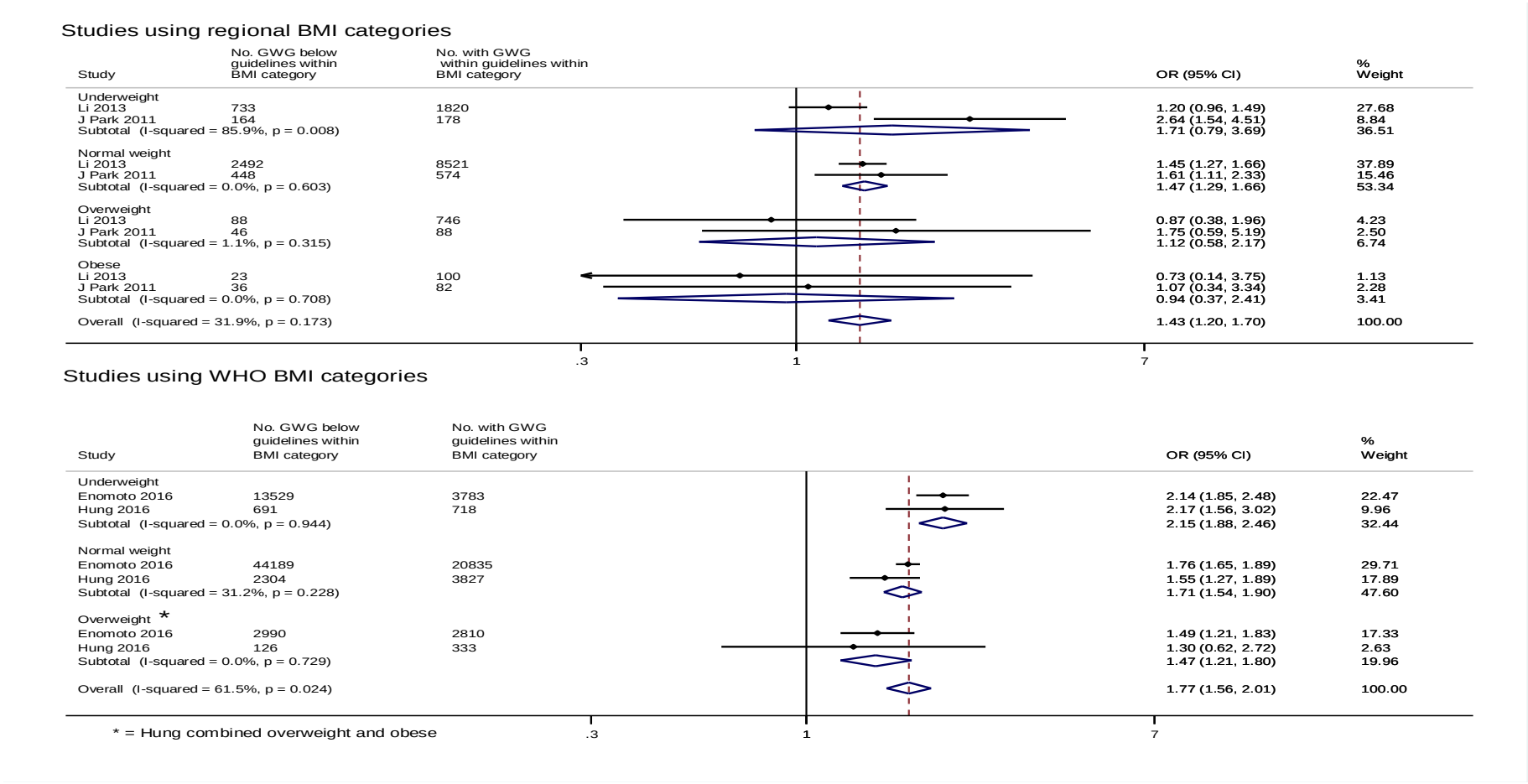
Reference group = women with recommended weight gain in each BMI group

Figure 1j. Caesarean delivery: GWG above guidelines



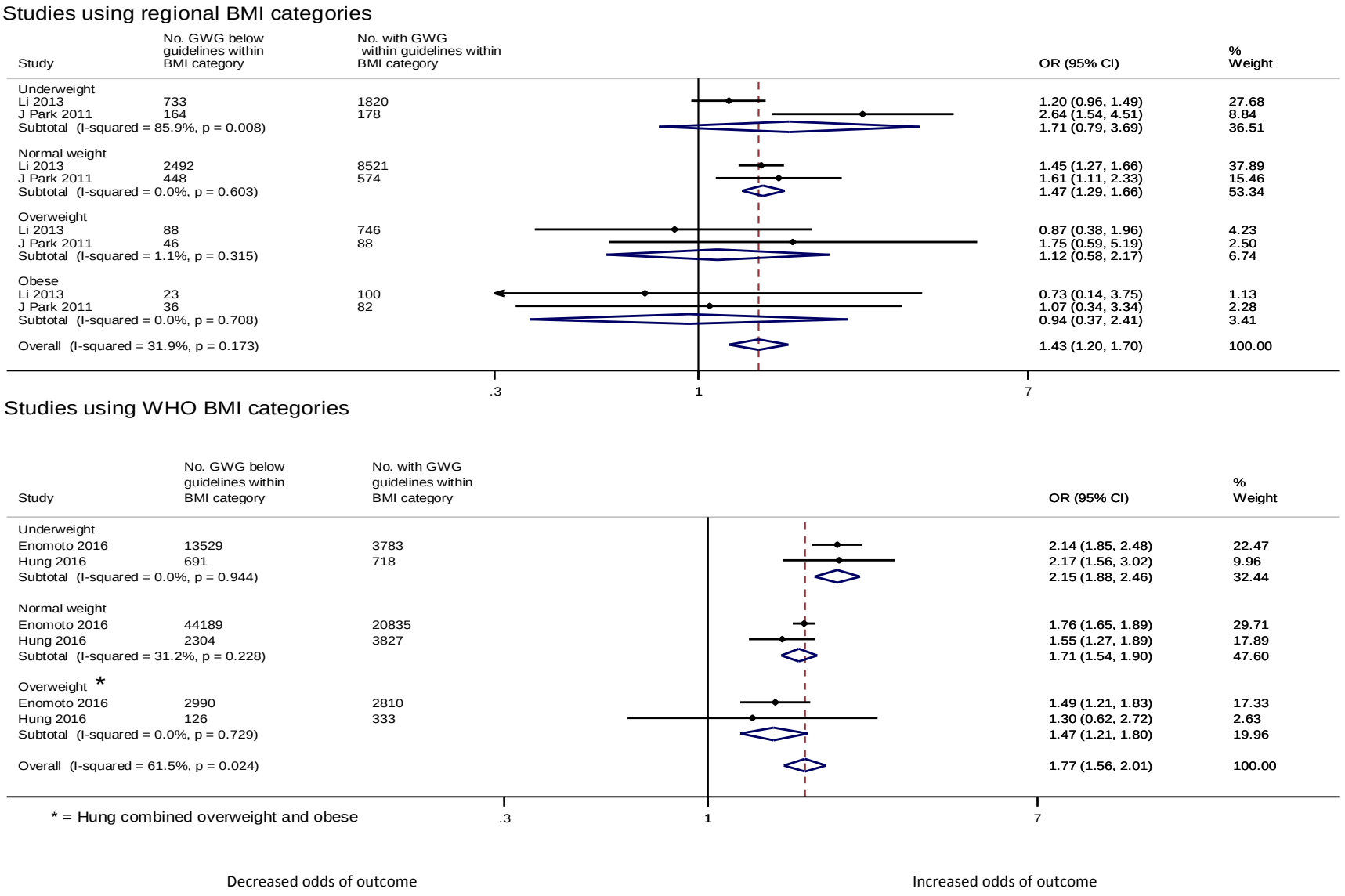
Additional file 6. Asian subgroup analysis: studies using local BMI categories (China, Korea) vs WHO BMI categories (Japan, Taiwan): summary of pooled OR for the association between gestational weight gain below and above guidelines for adverse outcomes

Figure 2a. Small for gestational age (SGA): GWG below guidelines



Reference group = women with recommended weight gain in each BMI group

Figure 2b. Small for gestational age (SGA): GWG above guidelines



Reference group = women with recommended weight gain in each BMI group

Figure 2c. Large for gestational age (LGA): GWG below guidelines

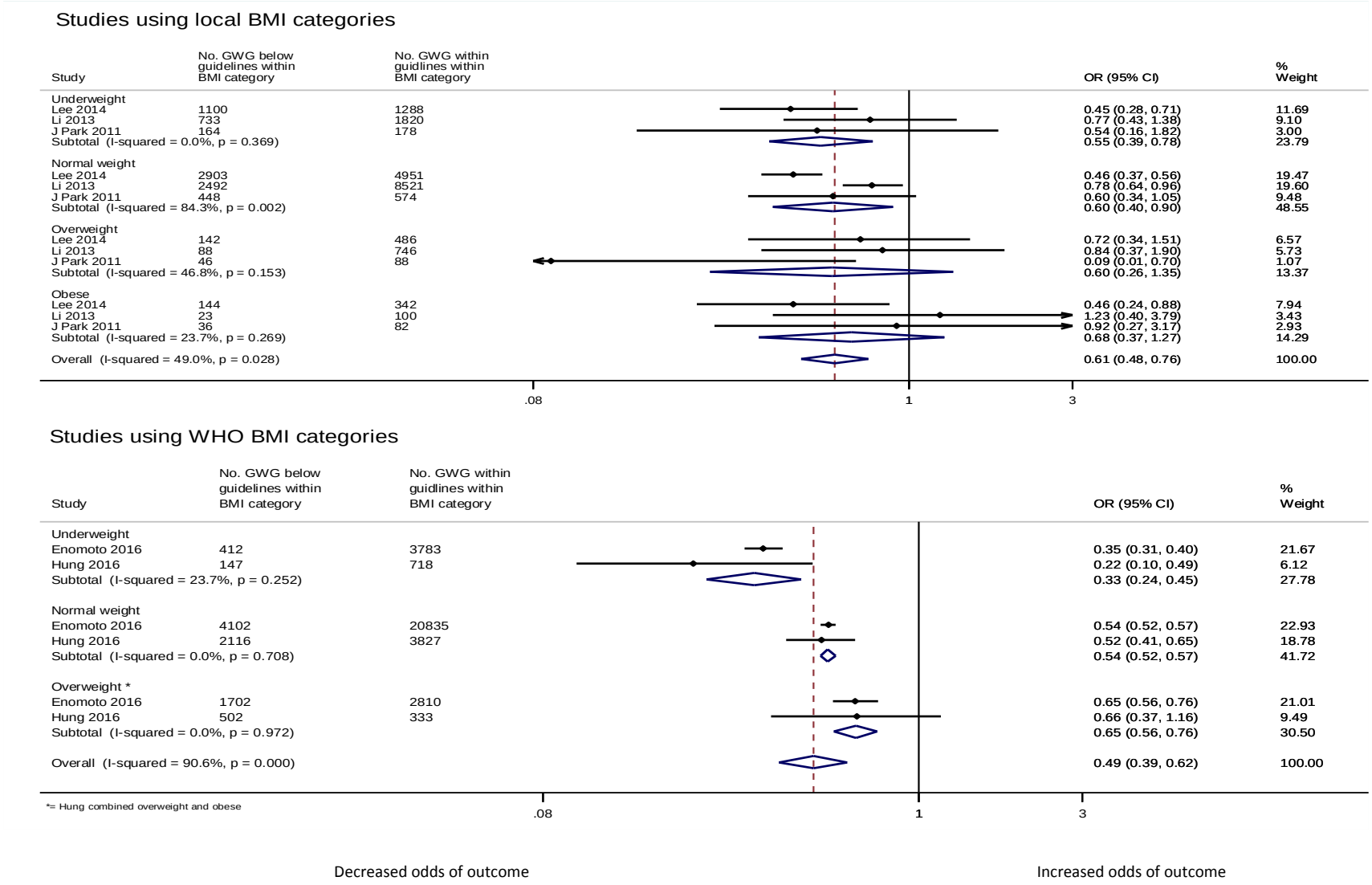
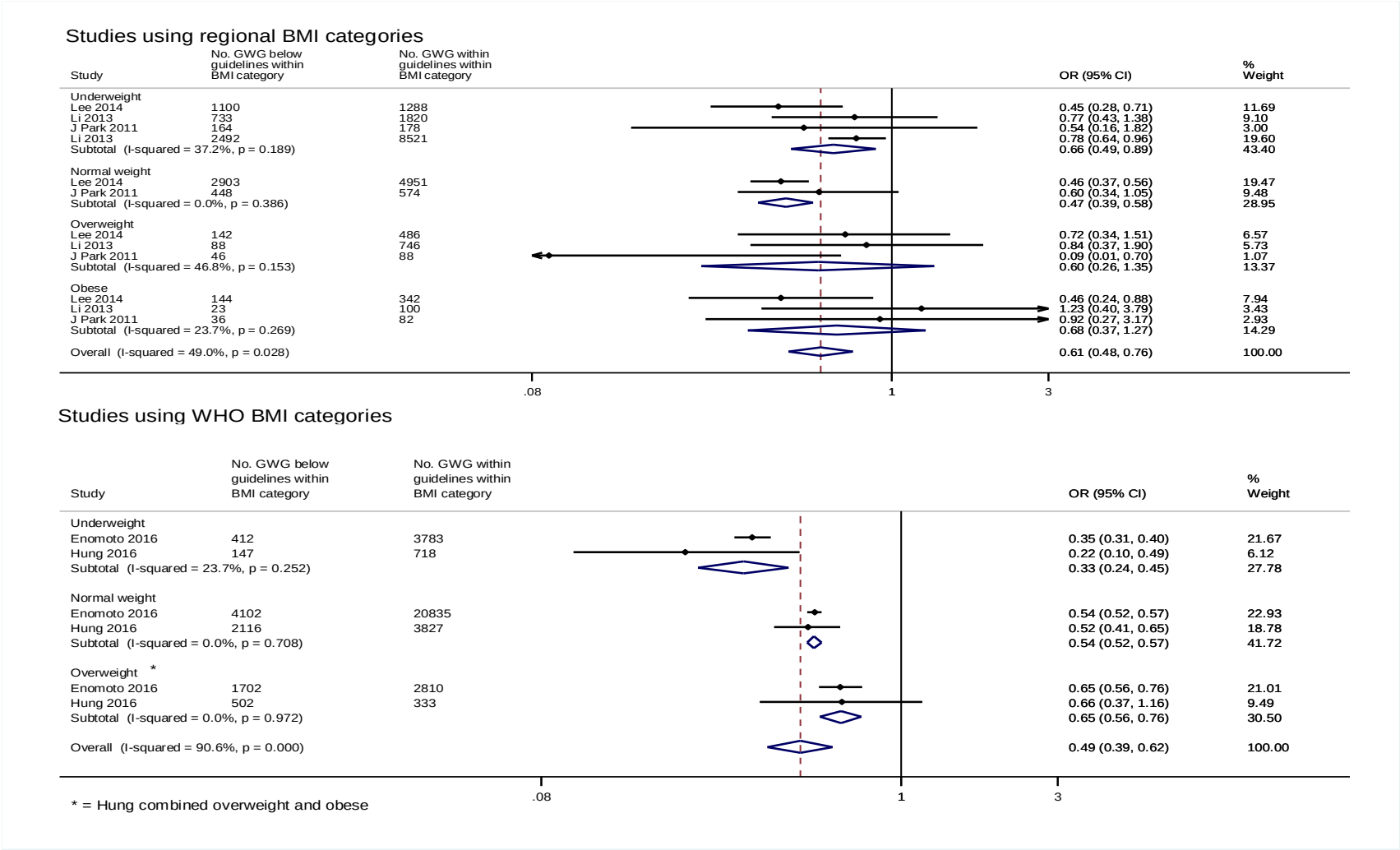


Figure 2d. Large for gestational age (LGA): GWG above guidelines

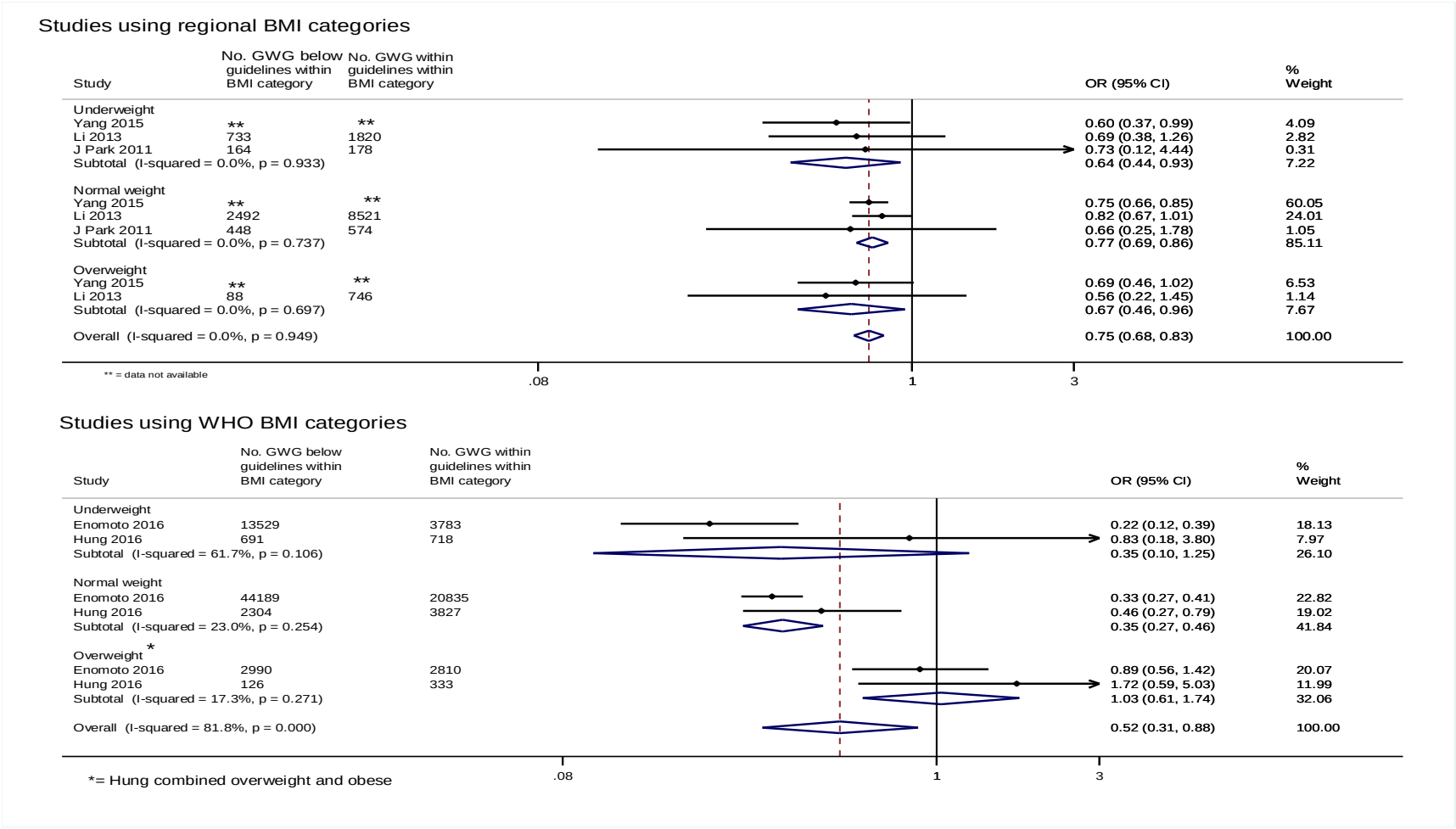


Decreased odds of outcome

Increased odds of outcome

Reference group = women with recommended weight gain in each BMI group

Figure 2e. Macrosomia: GWG below guidelines

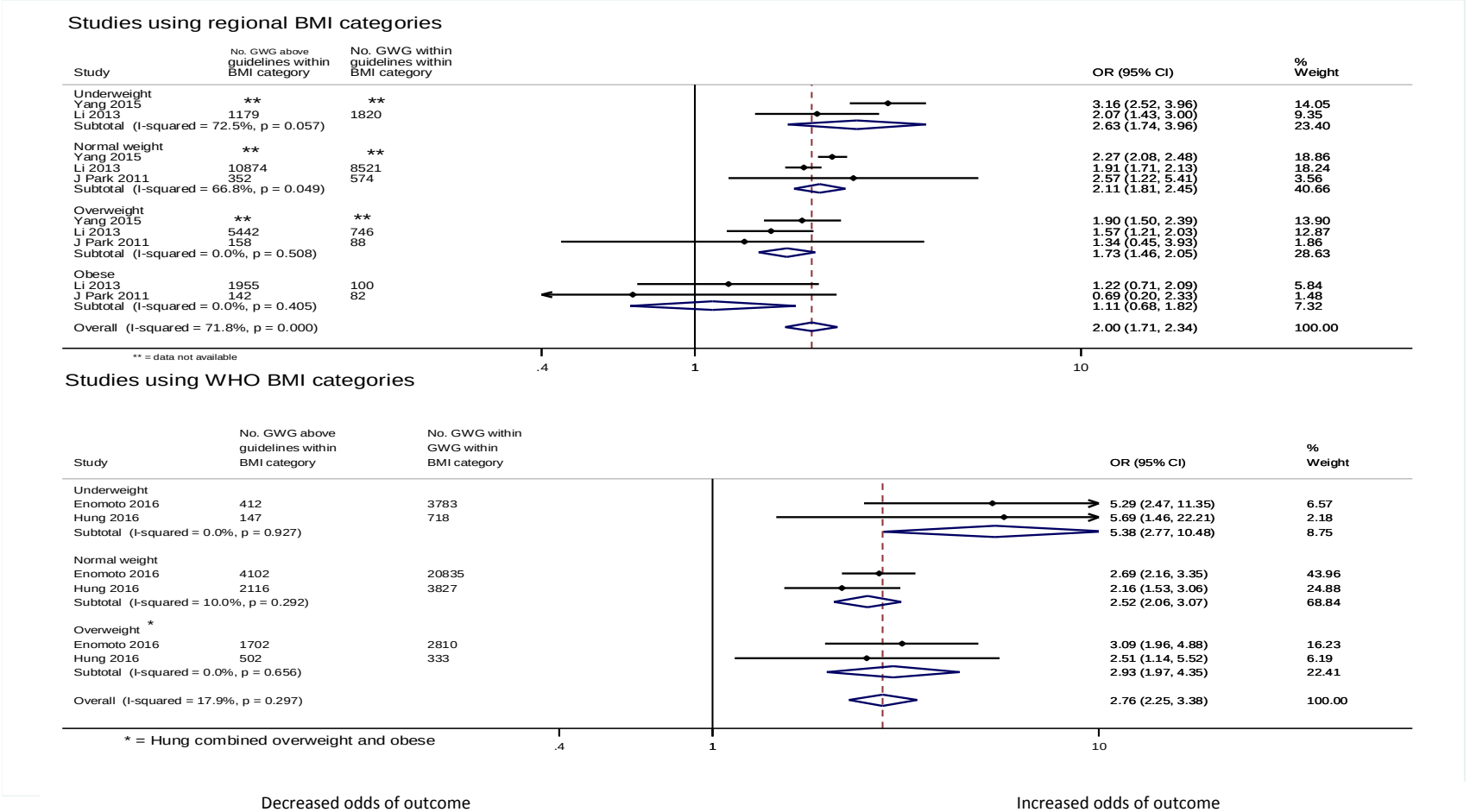


Decreased odds of outcome

Increased odds of outcome

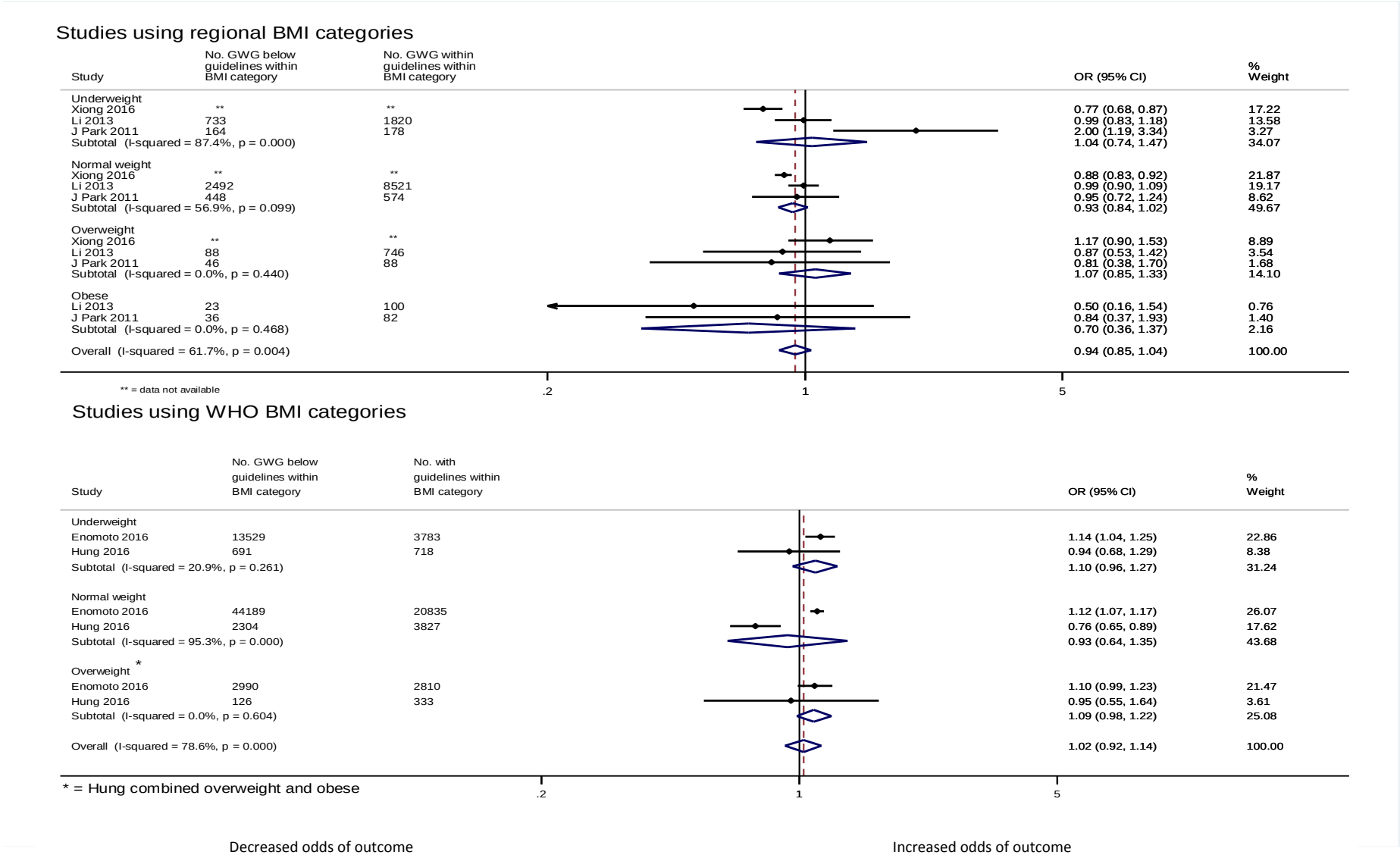
Reference group = women with recommended weight gain in each BMI group

Figure 2f. Macrosomia: GWG above guidelines



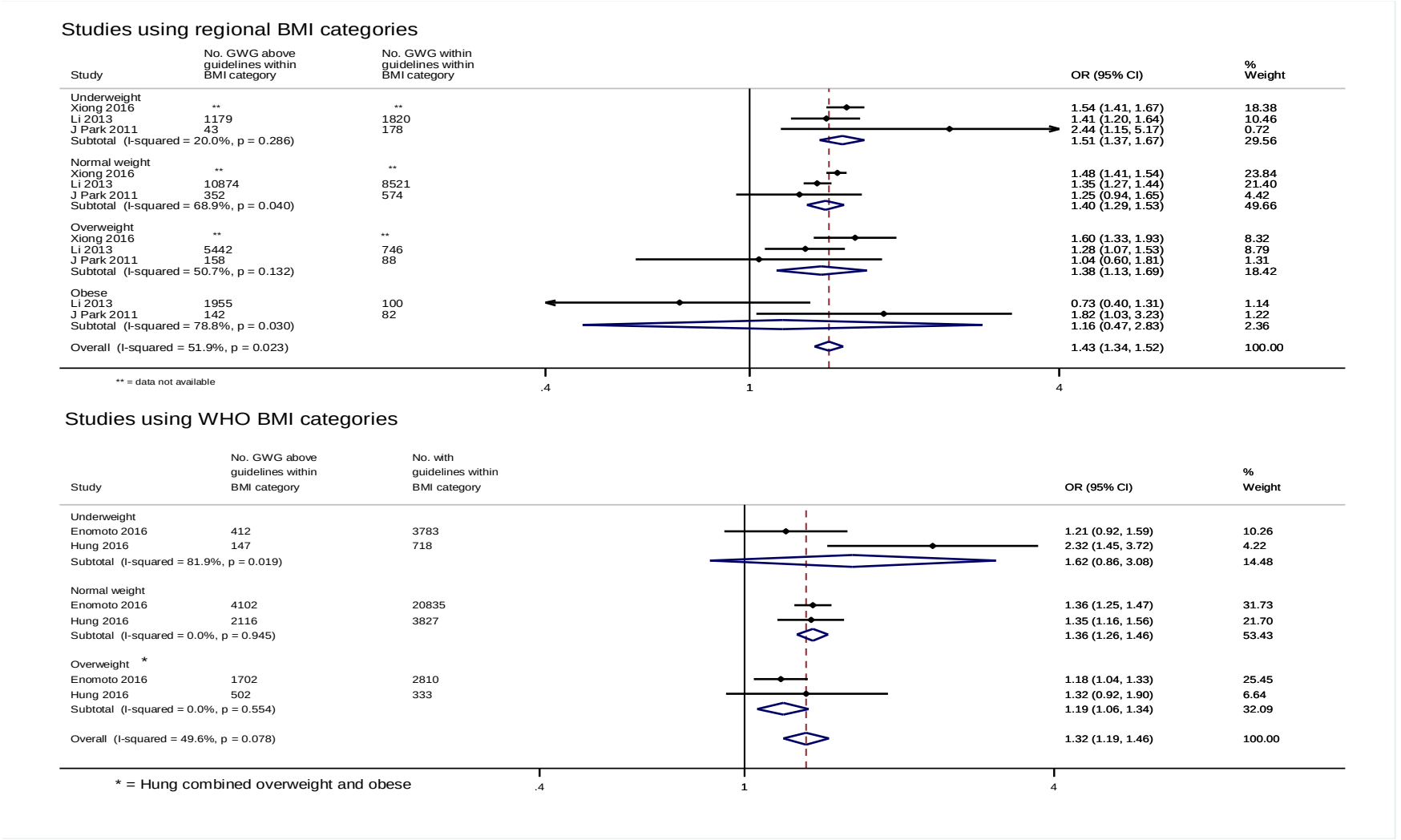
Reference group = women with recommended weight gain in each BMI group

Figure 2g. Caesarean section: GWG below guidelines



Reference group = women with recommended weight gain in each BMI group

Figure 2h. Caesarean section: GWG above guidelines



Decreased odds of outcome

Increased odds of outcome

Reference group = women with recommended weight gain in each BMI group

Additional file 7. Table 3. Body mass index at onset of pregnancy for Asian studies

Body mass index at onset of pregnancy, n (%)

Including all studies					
Country	Underweight	Normal weight	Overweight	Obese	Total
China	28330 (15)	145721 (76)	14905 (8)	2449 (1)	191405
Korea	3040 (16)	11979 (64)	1937 (10)	1652 (9)	18608
Japan	17724 (18)	69126 (71)	7502 (8)	2805 (3)	97157
Taiwan	1556 (14)	8247 (75)	961 (9)	209 (2)	10973
Excluding studies that selected for normal weight only (16) (study from China)					
China	28330 (16)	131945 (74)	14905 (8)	2449 (1)	177629
Korea	3040 (16)	11979 (64)	1937 (10)	1652 (9)	18608
Japan	17724 (18)	69126 (71)	7502 (8)	2805 (3)	97157
Taiwan	1556 (14)	8247 (75)	961 (9)	209 (2)	10973

Additional file 8. Table 4. Gestational weight gain during pregnancy for Asian studies

Gestational weight gain during pregnancy, n (%)

Including all studies				
Region	Below guidelines	Within guidelines	Above guidelines	Total
China	28748 (15)	61668 (32)	100989 (53)	191405
Korea	4983 (27)	7989 (43)	5636 (30)	18608
Japan	62005 (64)	28281 (29)	6871 (7)	97157
Taiwan	3156 (29)	4948 (45)	2869 (26)	10973

Additional file 9. Table 5. Metaregression*

Table 5a. Small for gestational age (SGA): GWG below guidelines for US/Europe

Variable (log OR)	Coefficient	p-value	Lower CI	Upper CI	I^2 (%)	p-value
Smoking (yes)	-0.0135231	0.056	-0.0274272	0.000381	0.10	0.0000
Mean maternal age (years)	-0.0781185	0.000	-0.1061379	-0.050099		
Nulliparous (yes)	0.0196059	0.000	0.0151648	0.0240469		

Table 5b. Small for gestational age (SGA): GWG below guidelines for Asia

Variable (log OR)	Coefficient	p-value	Lower CI	Upper CI	I^2 (%)	p-value
Smoking (yes)	0.1964278	0.369	-0.342288	0.7351436	36.44	0.5132
Mean maternal age (years)	-0.1933659	0.604	-1.148952	0.7622198		
Nulliparous (yes)	0.0111027	0.794	-0.0995421	0.1217475		

Table 5c. Small for gestational age (SGA): GWG above guidelines for US/Europe

Variable (log OR)	Coefficient	p-value	Lower CI	Upper CI	I^2 (%)	p-value
Smoking (yes)	-0.0104975	0.414	-0.0375238	0.0165287	62.11	0.3786
Mean maternal age (years)	-0.0052822	0.850	-0.0647809	0.0542165		
Nulliparous (yes)	-0.0064535	0.203	-0.0168867	0.0039797		

Table 5d. Large for gestational age (LGA): GWG below guidelines for US/Europe

Variable (log OR)	Coefficient	p-value	Lower CI	Upper CI	I^2 (%)	p-value
Smoking (yes)	-0.0197174	0.192	-0.0509173	0.0114826	0.00	0.0015
Mean maternal age (years)	0.0738492	0.021	0.0137145	0.1339839		
Nulliparous (yes)	-0.0202366	0.000	-0.0289771	-0.0114961		

Table 5e. Large for gestational age (LGA): GWG below guidelines for Asia

Variable (log OR)	Coefficient	p-value	Lower CI	Upper CI	I^2 (%)	p-value
Smoking (yes)	-0.0487653	0.814	-0.5884467	0.4909161	0.0	0.6590
Mean maternal age (years)	0.1316793	0.712	-0.7915934	1.054952		
Nulliparous (yes)	0.0074661	0.853	-0.0974589	0.1123911		

Table 5f. Large for gestational age (LGA): GWG above guidelines for US/Europe

Variable (log OR)	Coefficient	p-value	Lower CI	Upper CI	I^2 (%)	p-value
Smoking (yes)	-0.0169545	0.244	-0.0471117	0.0132027	68.31	0.0890
Mean maternal age (years)	-0.0543429	0.084	-0.1170754	0.0083897		
Nulliparous (yes)	0.0134203	0.025	0.0020001	0.0248405		

Table 5g. Large for gestational age (LGA): GWG above guidelines for Asia

Variable (log OR)	Coefficient	p-value	Lower CI	Upper CI	I^2 (%)	p-value
Smoking (yes)	0.0063775	0.839	-0.0704408	0.0831958	28.81	0.2477
Mean maternal age (years)	-0.373568	0.134	-0.9114196	0.1642835		
Nulliparous (yes)	-0.0246403	0.215	-0.0692884	0.0200078		

Table 5h. Macrosomia: GWG below guidelines for Asia

Variable (log OR)	Coefficient	p-value	Lower CI	Upper CI	I^2 (%)	p-value
Smoking (yes)	-0.0100196	0.985	-2.107265	2.087226	0.00	0.9691
Mean maternal age (years)	0.096737	0.810	-1.427319	1.620793		
Nulliparous (yes)	0.0087369	0.932	-0.3801903	0.3976642		

Table 5i. Macrosomia: GWG above guidelines for US/Europe

Variable (log OR)	Coefficient	p-value	Lower CI	Upper CI	I^2	p-value
Smoking (yes)	-0.0139481	0.287	-0.0414042	0.013508	56.87	0.4430
Mean maternal age (years)	-0.0744533	0.363	-0.2471216	0.0982151		
Nulliparous (yes)	-0.0089618	0.529	-0.039307	0.0213833		

Table 5j. Macrosomia: GWG above guidelines for Asia

Variable (log OR)	Coefficient	p-value	Lower CI	Upper CI	I^2 (%)	p-value
Smoking (yes)	0.1268428	0.615	-0.5955475	0.8492331	47.34	0.7675
Mean maternal age (years)	-0.2914988	0.390	-1.217734	0.6347363		
Nulliparous (yes)	0.0003095	0.994	-0.1157701	0.1163891		

Table 5k. Caesarean section: GWG below guidelines for Asia

Variable (log OR)	Coefficient	p-value	Lower CI	Upper CI	I^2	p-value
Smoking (yes)	0.1242494	0.461	-0.2990494	0.5475481	49.89	0.6020
Mean maternal age (years)	-0.3204323	0.301	-1.069926	0.4290615		
Nulliparous (yes)	-0.0060738	0.853	-0.0912339	0.0790863		

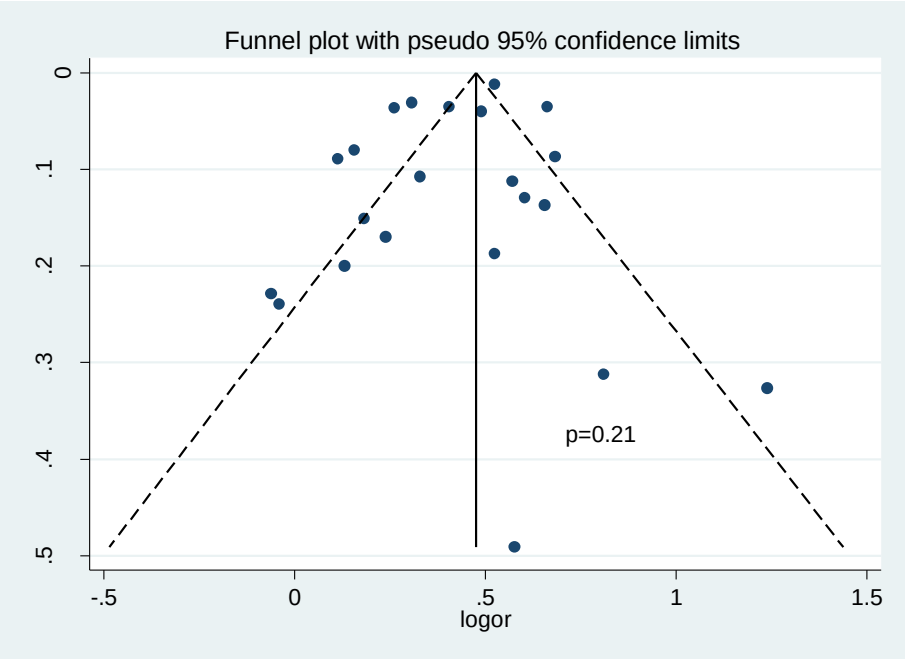
Table 5l. Caesarean section: GWG over guidelines for Asia

Variable (log OR)	Coefficient	p-value	Lower CI	Upper CI	I^2	p-value
Smoking (yes)	-0.1295935	0.288	-0.4235213	0.1643342	25.66	0.4990
Mean maternal age (years)	0.120274	0.328	-0.4205241	0.179976		
Nulliparous (yes)	-0.030367	0.186	-0.0832446	0.0225107		

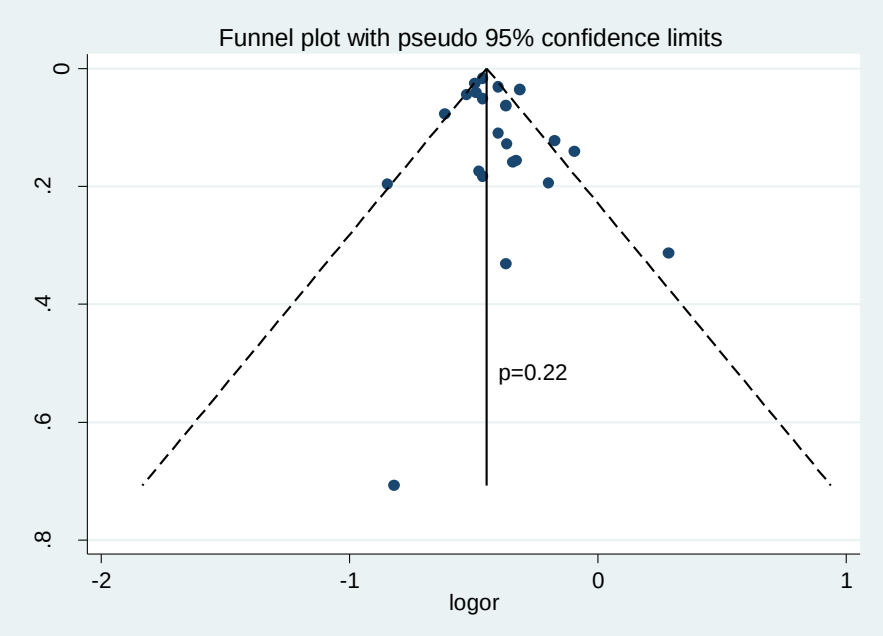
*REML estimate of between-study variance % residual variation due to heterogeneity. Proportion of between-study variance is explained using the Joint test for all covariates with Knapp-Hartung modification

Additional file 10. Figure 3. Publication bias

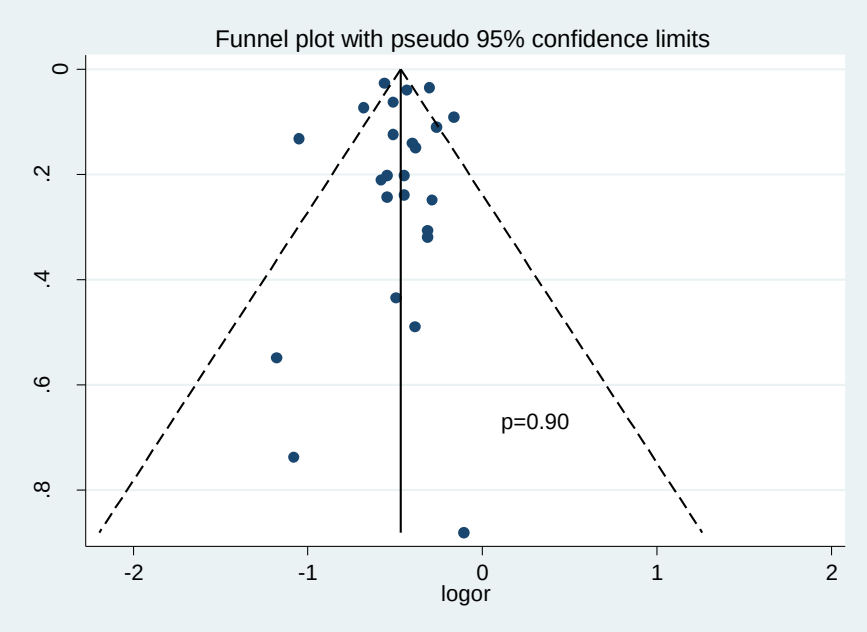
3a. SGA: GWG below guidelines for US/Europe



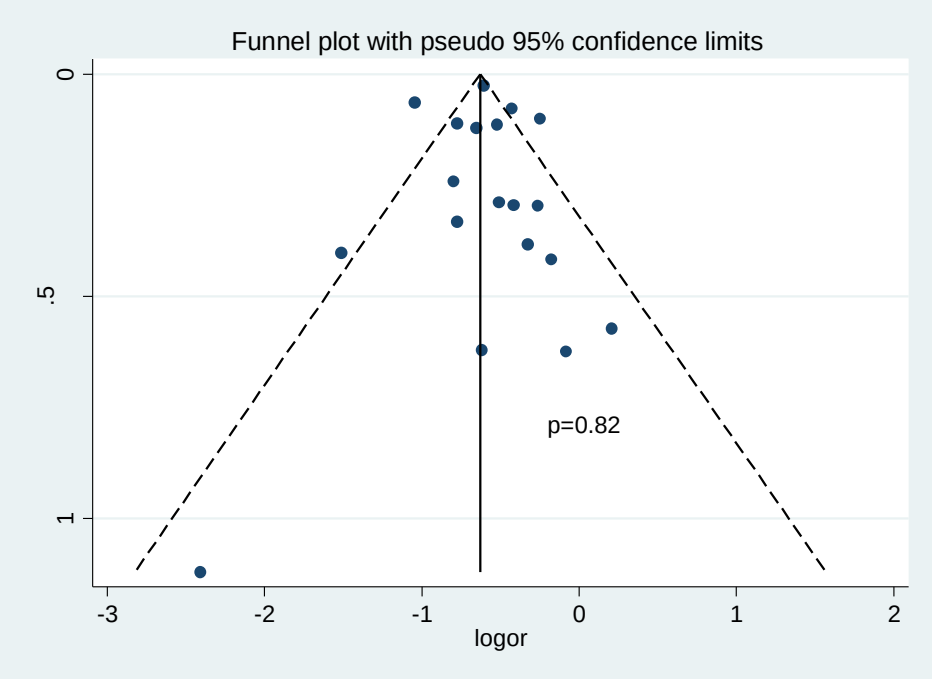
3b. SGA: GWG over guidelines for US/Europe



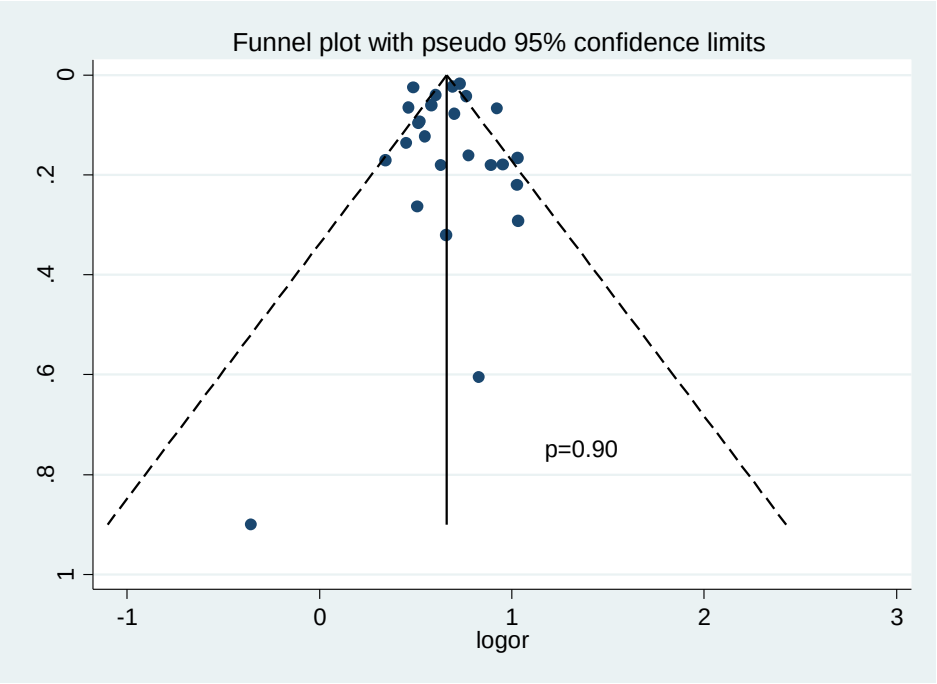
3c. LGA: GWG under guidelines for US/Europe



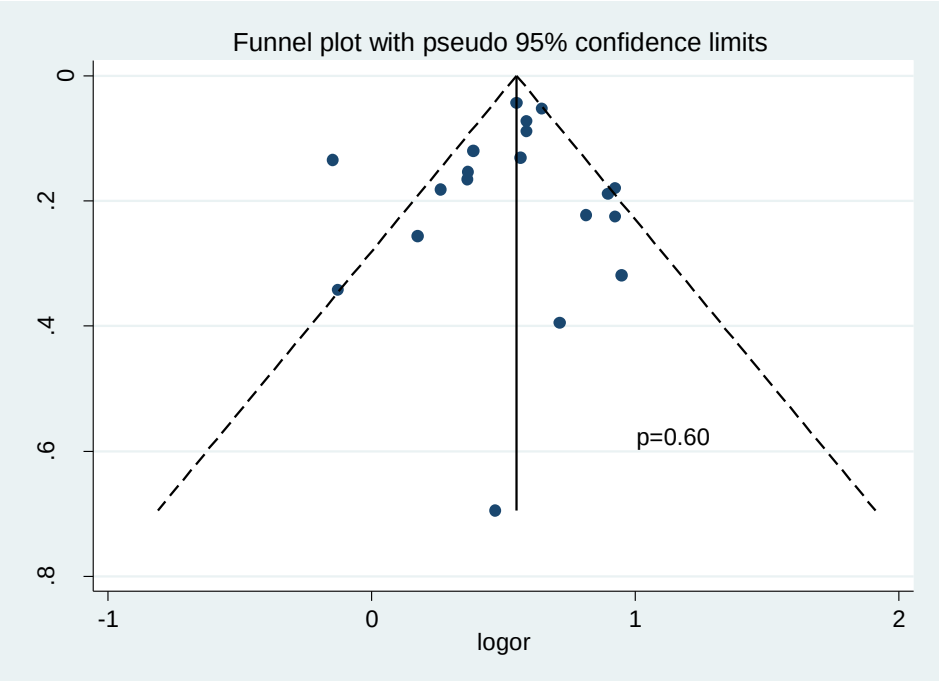
3d. LGA: GWG under guidelines for Asia



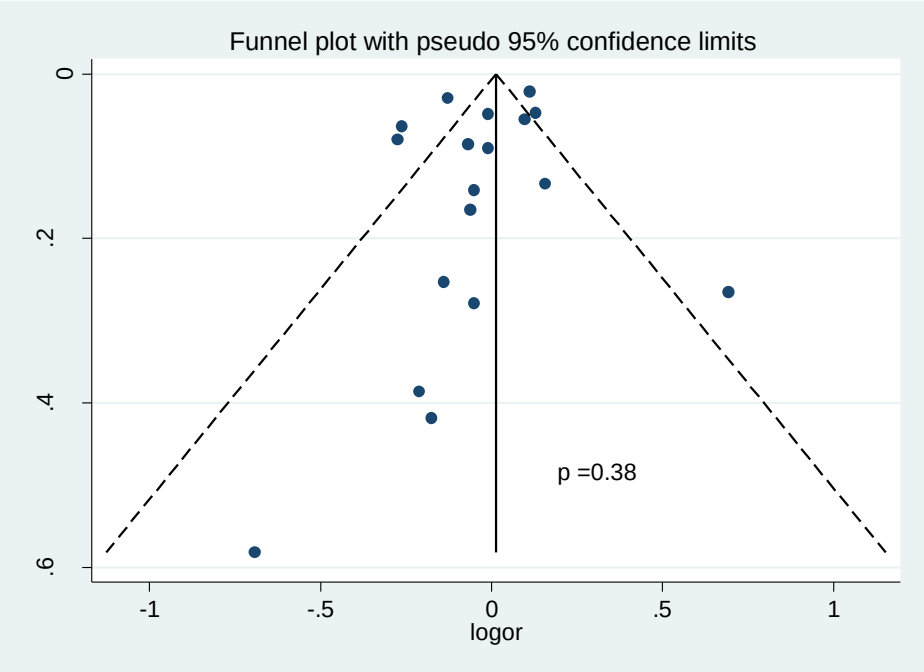
3e. LGA: GWG over guidelines for US/Europe



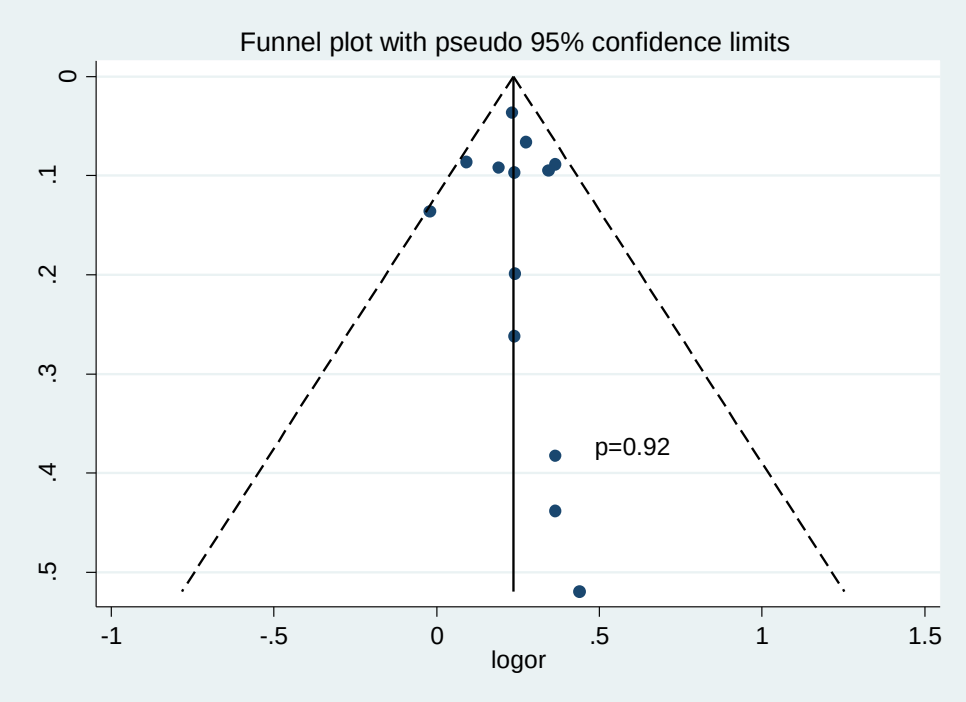
3f. LGA: GWG over guidelines for Asia



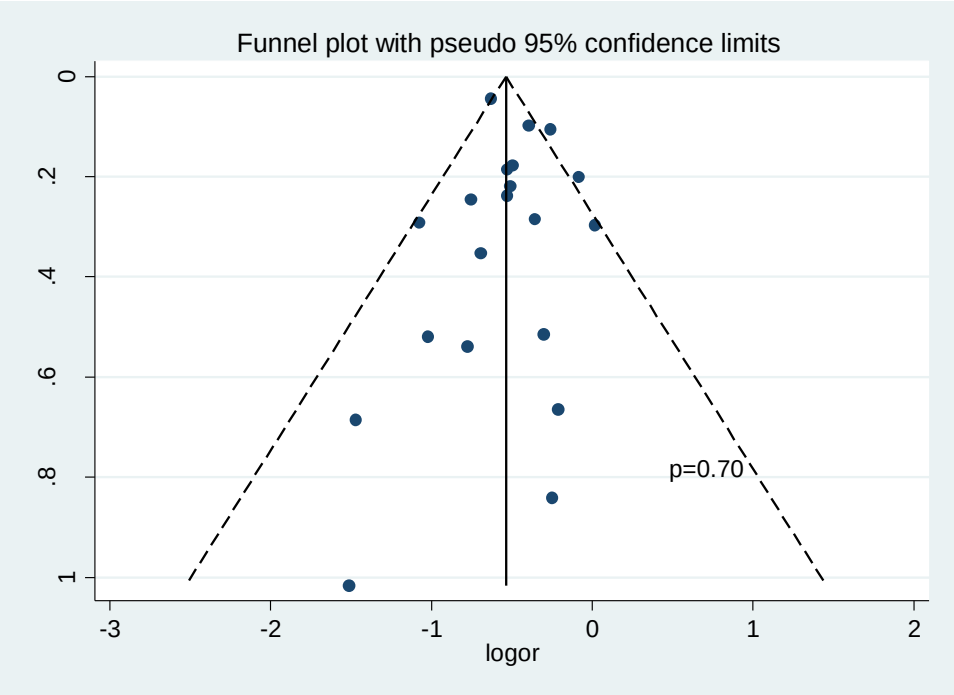
3g. Caesarean section: GWG under guidelines for Asia



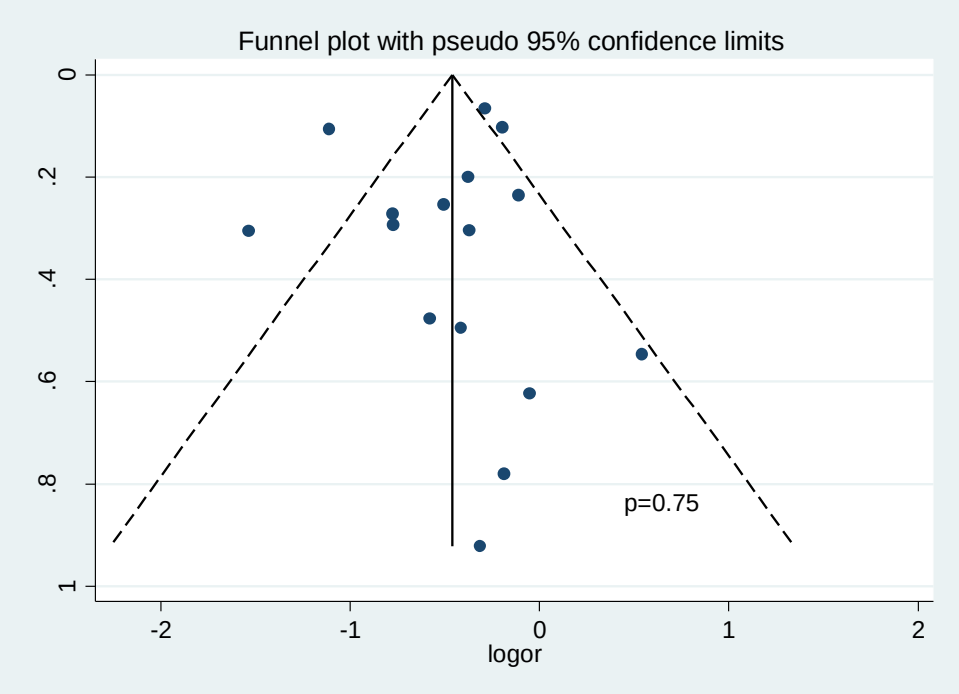
3h. Caesarean section: GWG over guidelines for Asia



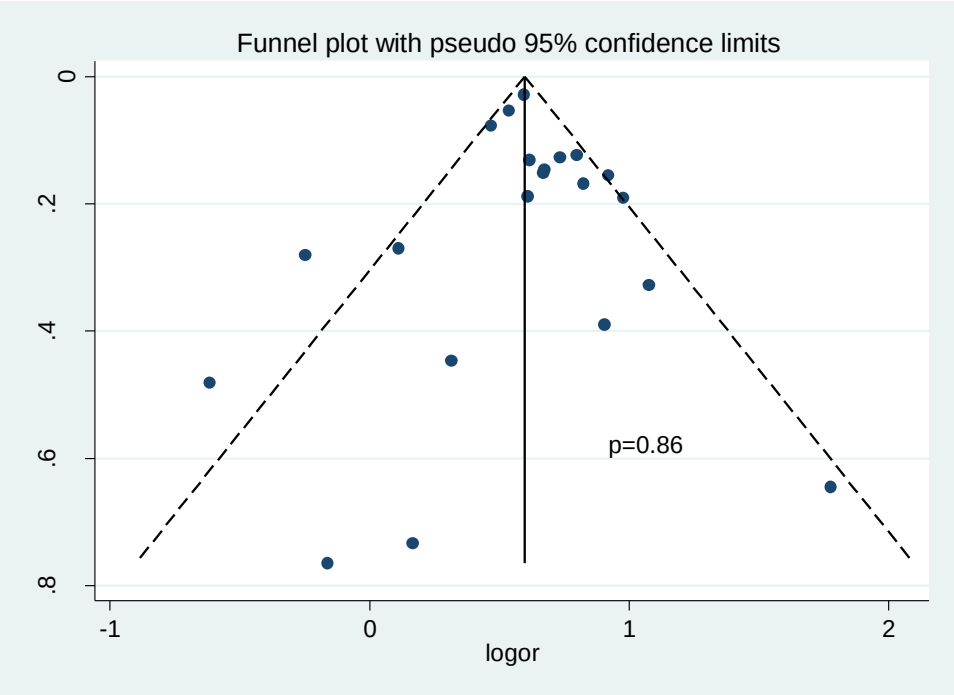
3i. Macrosomia: GWG below guidelines for US/Europe



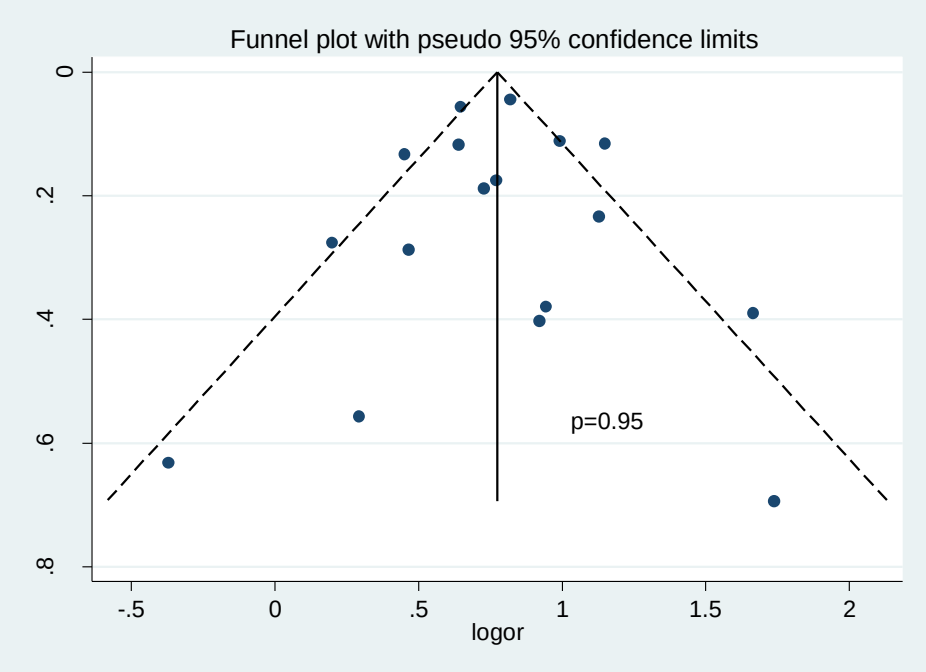
3j. Macrosomia: GWG below guidelines for Asia



3k. Macrosomia: GWG above guidelines for US/Europe



3l. Macrosomia: GWG above guidelines for Asia



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