Development of composite outcomes for individual patient data (IPD) meta-analysis on the effects of diet and lifestyle in pregnancy: a Delphi survey

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Running title: Composite for IPD synthesis on lifestyle interventions in pregnancy

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Objective: To develop maternal, fetal, and neonatal composite outcomes relevant to the evaluation of diet and lifestyle interventions in pregnancy by Individual Patient Data meta-analysis.

Design: Delphi survey

Setting: The International Weight management in Pregnancy (i-WIP) Collaborative Network.

Population/sample: Twenty six researchers from the i-WIP Collaborative Network from 11 countries.

Methods: A two-generational Delphi survey involving members of the International Weight management In Pregnancy (i-WIP) collaborative network (26 members, 11 countries) was undertaken to prioritise the individual outcomes for their importance to clinical care. The final components of the composite outcomes were identified using pre-specified criteria.

Main outcome measures: Composite outcomes considered to be important for the evaluation of the effect of diet and lifestyle in pregnancy.

Results: Of the 36 maternal outcomes, nine were prioritised and the following were included in the final composite: pre-eclampsia or pregnancy induced hypertension, gestational diabetes mellitus (GDM), elective or emergency caesarean section, and preterm delivery. Of the 27 fetal and neonatal outcomes, nine were further evaluated, with the final composite consisting of intrauterine death, small for gestational age, large for gestational age fetus and admission to Neonatal Intensive Care Unit (NICU).

Conclusion: Our work has identified the components of maternal, fetal, and neonatal composite outcomes required for assessment of diet and lifestyle interventions in pregnancy by IPD meta-analysis.

Keywords composite outcome, Delphi survey, diet, lifestyle, maternal, fetal, neonatal

Introduction

Diet and lifestyle interventions in pregnancy have the potential to influence both maternal, fetal, and neonatal outcomes (1). The effectiveness of these interventions on individual outcome measures such as pre-eclampsia, gestational diabetes and preterm delivery can be assessed with high precision through large trials (2). However, evaluation of the differential effects of these interventions on relevant subgroups, such as BMI, maternal age, parity, socioeconomic status and underlying medical condition require very large sample sizes. Individual Patient Data (IPD) meta-analysis has greater power to detect any differential treatment effect across groups than aggregate meta-analysis. It can model individual risk status across participants within trials, and thus explain variability in outcomes at the patient-level (3).

Identification of the appropriate outcome (s) for evaluation of the effect of diet and lifestyle in pregnancy is challenging. More than one outcome is considered to be clinically important. Furthermore, the analysis is often limited by the low incidence of individual outcomes. Composite outcome measures (4), (5) are often chosen in primary trials to overcome the above limitations. The development of such outcomes should be based on clear pre-specified criteria with transparency in reporting. A robustly developed composite outcome measure does not exist for diet and lifestyle intervention in pregnancy.

The International Weight management in Pregnancy (i-WIP) Collaborative Network was established to assess the effects of diet and lifestyle interventions in pregnant women on maternal, fetal, and neonatal outcomes by IPD meta-analysis (6). We developed maternal, fetal and neonatal composite outcome measures for evaluation of interventions based on diet and lifestyles by IPD meta-analysis.

Methods

The initial list of outcomes was based on systematic review of literature and a previous Delphi survey (7), (8). We undertook a two-stage Delphi survey (June – Sep 2013) that was conducted in line with current recommendations (9), (10) to prioritise the maternal, fetal, and neonatal outcomes for their relevance to clinical practice. We determined a priori to consider only those outcomes that were prioritised by the Delphi panel (Appendix S2) in our development of the composite outcomes. We also decided to exclude those outcomes that were a surrogate for maternal and fetal morbidity and mortality. We developed separate composite outcomes for maternal, fetal, and neonatal complications.

Reference panel

The Delphi panel consisted of members of the i-WIP Collaborative Network, which included researchers from 11 countries who have evaluated the effect of diet and lifestyle interventions in pregnancy by randomised trials. The network is supported by World Health Organisation (WHO), and is part of the global effort in bringing together researchers, clinicians and epidemiologists (6).

Delphi survey

In the first round of the survey, the panellists were approached in person or via email, and requested to score each of the identified maternal, fetal, and neonatal outcomes for their relevance to patient care when evaluating dietary and lifestyle interventions in pregnancy. For each outcome, we provided the median and interquartile ranges (IQR) for their importance as assessed by the previous Delphi panel (7). A nine-point Likert scale was used to evaluate the importance; a score of 9 is considered to be critical, and 1 is of limited importance to patient

144 care. E-mail reminders were sent to panellists if no responses were received after 2 weeks,
145 and the second reminder after 4 weeks.
146
147 In the first round, responders had an opportunity to add outcomes that they considered to be
148 important, but were not provided in the questionnaire. Once all responses were received, we
149 calculated medians and IQR for each outcome. Non-responders from the first round were not
150 invited to a subsequent round. An IQR of ≤2 in the second round was pre-specified to
151 indicate the consensus from the first round.
152
153 In the second round, all panellists were provided with the group scores and their individual
154 scores for each outcome. We maintained full anonymity between the panellists, and the
155 complete results were only known to the pollster (ER). Outcomes with a median score of over
156 7 and an IQR indicating consensus (≤ 2) were chosen for further evaluation for development
157 of the composite outcomes.
158
159 *Development of the composite outcome*
160 The final components for inclusion in the composite outcome were based on the following
161 criteria: considered to be critically important by the Delphi panel (score >7), of equal
162 importance, similar rates of occurrence, independent of each other, and evidence of same
163 direction of the effect with the intervention.
164
165 **Results**
166 *Characteristics of the Delphi panel*
167 The Delphi panel comprised of 26 clinicians and clinical academics from 11 countries with
168 expertise in diet and lifestyle interventions in pregnancy. This included 16 obstetricians, four

physiotherapists, two nutritionists, two midwives, one epidemiologist, and an endocrinology specialist. Majority of the panellists are involved in research in high income countries such as Australia (3), Belgium (2), Canada (1), Denmark (2), Finland (2), Netherlands (3), Norway (3), Spain (1), United Kingdom (5), United States (2) and two from an upper-middle income country Brazil (2) (11). Over 90% (24/26) of the panellists have experience of conducting randomised trials on diet and lifestyle interventions. Overall, the panel members have been responsible for five diet based, seven physical activity based, and 12 mixed intervention studies. Twenty six panellists ranked the maternal outcomes and 25 ranked the fetal and neonatal outcomes for their importance to patient care. Details on the rounds of the Delphi survey and development of composite outcomes are presented on the flow chart (Figure 1).

First round

All panellists, (100% 26/26) completed the questionnaire consisting of 34 maternal outcomes and 27 fetal and neonatal outcomes in the initial list. Fifteen (15/34, 44%) maternal outcomes were scored as critical to patient care and 19 (19/34, 56%) outcomes were scored as important but not critical (Figure 2). The outcome threatened miscarriage was not considered to be critical to patient care (median <6).

Eleven (41% 11/27) fetal and neonatal outcomes were scored as critical to patient care and 16 (59%, 16/27) outcomes were scored as important (Figure 3).

The panellists suggested consideration of pre-eclampsia and pregnancy induced hypertension to be two distinct outcomes and this was added to the list of rating in the second round. Similarly, the panel advised that elective and emergency caesarean section to be considered

separately, and these were added to the list for scoring in the second round. Neurodevelopment at 2 years of age and fetal cord blood (insulin or c-peptide) were added to the second round based on the recommendations of the panellists.

The individual scores showed some minimal variation (IQR≤2) for twelve of the critical maternal outcomes, namely pre-eclampsia, pregnancy induced hypertension, gestational diabetes mellitus, preterm delivery, elective caesarean, emergency caesarean section, thromboembolism, admission to High Dependency Unit (HDU)/Intensive Therapy Unit (ITU), miscarriage, need for resuscitation at delivery, physical activity, and dietary behaviour. For the eleven critical fetal and neonatal outcomes there was minimal variation (IQR≤2) shown in: Intrauterine death small for gestational age, large for gestational age, Admission to neonatal intensive care unit (NICU), Shoulder dystocia, >1 perinatal complication, birth trauma, long term neurological sequelae, long term metabolic sequelae, hypoglycaemia, and respiratory distress syndrome.

Second round

Twenty-five (96%, 25/26) panellists took part in the second iteration. Eighteen (18/36, 50%) maternal outcomes had a median score of ≥7 and were considered to be critical to patient care, while 18 outcomes had a median score of ≥4 and were considered to be important. There was a narrowing of IQR for the seventeen of the outcomes showing consensus between panellists (Figure 2).

Eleven (38%, 11/29) fetal and neonatal outcomes scored between 7 and 9, and were considered to be critical to patient care. The fetal and neonatal outcomes that progressed to the second round are shown in Figure 3.

The scoring of maternal, fetal, and neonatal outcomes between the previous and the current panel was overall congruent (Appendix S1). Miscarriage, physical activity, postpartum weight retention, quality of life, and breast feeding were considered to be critically important in the current Delphi panel but only important in the previous panel. Instrumental delivery and failed instrumental delivery were critically important in previous Delphi panel but only important in this panel. Threatened miscarriage was of limited importance to patient care in the previous Delphi but considered as important by the current Delphi panel. Abnormal cord pH was critically important in the previous panel but only important in the current panel.

Components of the Composite Outcomes

Nine maternal and nine fetal and neonatal outcomes with a score ≥8 were evaluated for their inclusion as components of the composite outcomes (Figure 2 and 3). The following maternal components were included: pre-eclampsia or pregnancy induced hypertension, gestational diabetes mellitus (GDM), elective or emergency caesarean section, and preterm delivery. Outcomes that occurred rarely such as thromboembolism, not well reported such as admission to HDU or ICU, or surrogate for maternal morbidity such as gestational weight gain were not included in the final list.

The following fetal and neonatal components fulfilled the selection criteria for inclusion in the composite: intrauterine death, small for gestational age fetus, large for gestational age

fetus, and admission to NICU. Given the long time frame required to assess the risk of long-term metabolic sequelae and neurodevelopment of the baby, they were excluded from the neonatal composite. Rare outcomes such as shoulder dystocia and birth trauma significant overlap with large for gestational age fetus, and were poorly reported, leading to their exclusion. We also excluded the outcome of more than one perinatal complication, as it was considered to be significantly dependent on the other neonatal outcomes.

Discussion

Main findings

We developed composite outcomes for evaluation of diet and lifestyle interventions in pregnancy by IPD meta-analysis. We applied robust and validated methods for this work and prioritised the outcomes through consensus involving leading multidisciplinary clinicians and researchers in the field. The detailed and transparent reporting of the process of composite outcomes development will allow researchers conducting IPD to evaluate and compare the effect of intervention on the overall composite outcomes and their individual components.

Strengths

To our knowledge, this is the first formally developed composite measure for evaluation of diet and lifestyle interventions during pregnancy in IPD meta-analysis. One of the major strengths of this project was the use of two iterative Delphi surveys. The second survey validated the findings of the primary panel (1) thereby increasing the reliability and reproducibility of the developed composites outcomes. The panels were fully independent and involved experts with relevant expertise. The second Delphi panel widened the area of expertise by involving researchers from wider disciplines (nutritionist, physical activity experts, midwives) and had a global reach (Canada, US, Brazil, Finland, Norway, Denmark,

The Netherlands, Belgium, Spain, Australia and UK). Furthermore, the majority of the panellists have experience in clinical trials in this topic. We had excellent response rate of over 90% in both rounds.

The list of maternal, fetal, and neonatal outcomes used in the survey was firstly identified through a systematic review and evaluated by the first panel (1). The Delphi panel methodology improved the panel's work and avoided counterproductive group dynamics such as domination of discussion by senior members (12). Finally, we evaluated all critically important outcomes in a systematic manner against pre-specified rigorous criteria (13) prior to their inclusion in the final composite outcomes.

Limitations

The findings are based on individual and group opinions and are strongly dependant on the composition of the panel. We have minimised any resulting bias by validating the findings of one panel against a new panel of international experts in the field. Similarly, a different consensus group may have chosen other components for inclusion in the composite. The optimal size of a Delphi panel to generate consensus is not known. We decided to have a panel of moderate size, as (10-20) (14), (15) a small panel might not represent a good range of opinions on the topic, and a larger panel may lead to low response and high drop-out rates (15).

Interpretation

One of the main challenges in using composite outcomes in IPD meta-analysis on diet and lifestyle interventions in pregnancy is the variation in the outcomes reported. The trials included in the i-WIP IPD meta-analysis (~~34~~ 36 trials with data over ~~8000~~ 12,000 women)

vary in the reporting of components of the composite outcomes. Some of the clinically relevant outcomes such as neurodevelopment and thromboembolism were not reported in primary studies. Similarly maternal admission to HDU or ICU was not widely reported.

Our decision on the final inclusion of components in the composite was a balance between rigorous and pragmatic criteria. We aimed to adhere to the pre-specified criteria as much as possible, but also refrained from including components that were not widely reported. Although outcomes such as admission to NICU may be clinician driven, they are also the common outcomes uniformly reported across trials.

Conclusion

Any published IPD meta-analyses on diet and lifestyle interventions should provide the effect on composite outcomes and on individual outcomes. In order to maintain methodological rigour all individual components of the composites should be inspected separately during the secondary analysis (16) This will allow healthcare professionals and patients to identify whether any outcomes are disproportionately driving the findings on the composite.

The restrictions in IPD meta-analyses due to variation in outcome reporting could be reduced by two strategies. Firstly, by developing minimum core outcome sets for reporting in primary clinical trials. The COMET and the CROWN initiatives have identified the need for such core outcome sets (17), (18). Secondly, by designing prospective IPD meta-analyses with pre-specified relevant outcomes. The Global Obstetric Research Network (GONet) has prioritised this area, and has supported such a strategy for preterm research (19). Similar global initiatives are required to standardise outcome reporting for research on diet and lifestyle interventions in pregnancy.

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Author's contribution

ER performed literature search and Delphi survey questionnaire design with ST. The two-generation Delphi survey was conducted and analysed by ER. ST, KSK and JGC, HT, SY, CAV, GR, RBC, MP, JD, RD, AB, MNMP, LH, GXS, AS, RL, TIK, SP, LP, TTS, NEB, SNS, ST, NRWG, AER, BWM, AC assisted in development of the composite outcomes. ER, ST and KSK helped to formulate the question and interpret the findings. ER wrote the original draft of the paper assisted by MD and ST. ER, MD, ST, KSK, JGC, HT, SY, CAV, GR, RBC, MP, JD, RD, AB, MNMP, LH, GXS, AS, RL, TIK, SP, LP, TTS, NEB, SNS, ST, NRWG, AER, BWM, AC helped to revise the final draft.

Declaration of interest

The authors report no conflict of interest.

Details of ethics approval

Ethical approval was not required for this project.

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Appendices

Appendix S1. List of maternal, fetal, and neonatal outcomes considered to be relevant for studies on diet and lifestyle in pregnancy

Appendix S2. Maternal and fetal outcomes ranked by the previous Delphi survey of 19 panelists

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Figures

Figure 1. Flow chart of outcome selection in the Delphi survey of prioritisation of maternal, fetal, and neonatal outcomes relevant to patient care with diet and lifestyle interventions in pregnancy

Figure 2. Prioritisation of maternal outcomes relevant to clinical care of mothers on diet and lifestyle interventions

Figure 3. Prioritisation of fetal and neonatal outcomes relevant to clinical care of mothers on diet and lifestyle interventions