The effect of dietary and lifestyle advice for pregnant women who are overweight or obese on maternal diet and physical activity: The LIMIT randomised trial.

Professor Jodie Dodd
• 35% of women aged 18-45 years are overweight or obese (Cameron 2003)

• Up to 50% of pregnant women in South Australia have a BMI greater than 25kg/m² (Schiel 2012)

• Risk of adverse health outcomes increase with increasing BMI
  • Medical complications
  • Labour & Birth complications
  • Adverse infant health outcomes
Adverse Maternal Outcomes

Risk of adverse outcomes by BMI category; normal BMI reference range (Dodd 2011)
Adverse Neonatal Outcomes

Risk of adverse outcomes by BMI category; normal BMI reference range (Dodd 2011)
Early-life factors and risk of obesity

- Maternal obesity
  - 2- to 6-fold increase in risk of childhood obesity

- Gestational weight gain
  - 2-fold increase in risk of pre-school obesity

- High infant birth weight
  - 2-fold increase in risk of childhood obesity
Assessment of Diet Quality

- **Tools:**
  - Food frequency questionnaire
  - Food diary

- **Components:**
  - Energy intake
  - Food groups
  - Macro and micronutrient intake
  - Dietary Quality
    - Healthy Eating Index
  - Glycaemic Index
Diet quality during pregnancy

- Women who are overweight or obese
  - Poorer diet quality during pregnancy compared with women of normal BMI
  - Effects persistent into the early postpartum period (Moran et al 2012)
  - Reduced intake of grains, fruits & vegetables, iron and folate
  - Increased overall energy intake and percentage energy derived from fats

- Clinical effect of poorer diet quality
  - Increased risk of pregnancy complications
    - Pre-eclampsia
    - Gestational diabetes
Randomised trials

- Antenatal Dietary Interventions among women who are overweight or obese
  - 9 randomised trials
  - 3,069 women
  - Uncertain benefit in limiting gestational weight gain
  - No differential effect according to intensity of the intervention
  - Specific dietary changes achieved following intervention reported in only 3 small randomised trials
Assessment of Physical Activity

- **Tools:**
  - Physical Activity questionnaires
  - Pedometer
  - Accelerometer

- **Components:**
  - Leisure activity
  - Household activity
  - Commuting activity
  - Work related activity
Physical activity during pregnancy

- Beneficial effects of physical activity during pregnancy
- Over the course of pregnancy physical activity declines in women of all BMI categories
  - This effect is more pronounced for women who are overweight or obese
  - Importance of assessing household & care-giving activities which may increase to up to 65% of energy expenditure in pregnancy among women who are overweight or obese
Antenatal Exercise Interventions among women who are overweight or obese

- 6 randomised trials
- 317 women
- Modest difference of 0.57kg in gestational weight gain associated with intervention provision
- Most outcome measures reported relate to cardiovascular fitness
- Very little information available related to clinical outcomes or changes achieved in physical activity across pregnancy
For pregnant women who are overweight or obese, what is the effect of an antenatal dietary and lifestyle intervention on maternal diet and physical activity?
Design & Participants

- Multi-centre, randomised, controlled trial
- Public maternity units across metropolitan Adelaide, SA
  - All women had their height & weight measured, & BMI calculated
- Inclusion
  - Singleton pregnancy
  - BMI >25kg/m²
  - Gestational age 10^+0 to 20^+0 weeks
- Exclusion
  - Prior diagnosis of type 1 or 2 diabetes
Lifestyle Advice

**Dietary Advice**
- Balance carbohydrates, protein, fat
- Increase consumption of fibre
- Consume 2 serves fruit, 5 serves vegetables, & 3 serves dairy daily
- Reduce intake of foods high in refined carbohydrates & saturated fats

**Exercise Advice**
- Increase physical activity
- Primarily through increasing walking and incidental activities

**Goals and Support**
- Set achievable goals
- Self monitor progress
- Identify barriers to behavioural changes
- Identify enablers to behavioural changes
Intervention Sessions

- Detailed dietary & physical activity history
- Individualised information provided
  - Dietary goals
    - 2 serves fruit, 5 serves vegetables, 3 serves dairy daily
  - Meal plans
  - Healthy recipes
  - Simple food substitutions
    - Reducing sugar sweetened beverages and fruit juice
    - Reducing added sugar
    - Reducing foods high in refined carbohydrates & saturated fats
    - Low-fat alternatives
  - Healthy snack & eating out options
Lifestyle Advice

**Research Dietitian**
- Initial face to face planning session at trial entry
- Follow-up face to face session at 28 weeks gestation

**Research Assistant**
- Telephone sessions at 22, 24, and 32 weeks gestation
- Face to face session at 36 weeks gestation
Standard Care

- Ongoing clinical care from health-care providers at their planned hospital of birth
- This care does not currently include the routine provision of dietary and lifestyle information, or advice on gestational weight gain
Pre-specified Outcomes

- **Primary**
  - Incidence of infants born large for gestational age

- **Secondary**
  - Infant
  - Maternal
  - **Dietary intake**
  - **Physical activity patterns**
    - Psychological well-being and quality of life
    - Costs of health care
Dietary Questionnaires

- Harvard Semi-quantitative Food Frequency Questionnaire (the Willett Questionnaire)
- Completed at trial entry, 28 & 36 weeks gestation, and 4 months postpartum
- Daily nutrient intake estimated using Australian food composition tables
- Healthy Eating Index
- Glycaemic Index and Load
<table>
<thead>
<tr>
<th>Components</th>
<th>Score</th>
<th>Minimum score</th>
<th>Maximum score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total fruit (includes 100% juice)</td>
<td>0-5</td>
<td>No fruit</td>
<td>≥ 0.8 C equiv/1000 kcal</td>
</tr>
<tr>
<td>Whole fruit (not juice)</td>
<td>0-5</td>
<td>No whole fruit</td>
<td>≥ 0.4 C equiv/1000 kcal</td>
</tr>
<tr>
<td>Total vegetables</td>
<td>0-5</td>
<td>No vegetables</td>
<td>≥ 1.1 C equiv/1000 kcal</td>
</tr>
<tr>
<td>Dark green/orange vegetables; legumes</td>
<td>0-5</td>
<td>No dark green/orange veg or legumes</td>
<td>≥ 0.4 C equiv/1000 kcal</td>
</tr>
<tr>
<td>Total grains</td>
<td>0-5</td>
<td>No grains</td>
<td>≥ 0.8 C equiv/1000 kcal</td>
</tr>
<tr>
<td>Whole grains</td>
<td>0-5</td>
<td>No whole grains</td>
<td>≥ 85 g equiv/1000 kcal</td>
</tr>
<tr>
<td>Milk</td>
<td>0-10</td>
<td>No milk</td>
<td>≥ 1.3 C equiv/1000 kcal</td>
</tr>
<tr>
<td>Meat and beans</td>
<td>0-10</td>
<td>No meat or beans</td>
<td>≥ 70 g equiv/1000 kcal</td>
</tr>
<tr>
<td>Oils (unsaturated)</td>
<td>0-10</td>
<td>No oil</td>
<td>≥ 12 g per 1000 kcal</td>
</tr>
<tr>
<td>Saturated fat</td>
<td>0-10</td>
<td>≥ 15% of energy</td>
<td>≤ 7% of energy</td>
</tr>
<tr>
<td>Sodium</td>
<td>0-10</td>
<td>≥ 2.0 g per 1000 kcal</td>
<td>≤ 0.7 g per 1000 kcal</td>
</tr>
<tr>
<td>Calories from SOFAAS</td>
<td>0-20</td>
<td>≥ 50% of energy</td>
<td>≤ 20% of energy</td>
</tr>
<tr>
<td>TOTAL</td>
<td>100</td>
<td>HEI &gt; 80 = Good; 50-80 = Needs improvement; &lt; 50 = Poor</td>
<td></td>
</tr>
</tbody>
</table>
Glycaemic Load and Index

- Analysed from the Food Frequency Questionnaire using Food Works Nutrient Analysis Software
- Incorporation Australian Food Composition tables and published glycaemic index values
Physical Activity Questionnaires

- Short Questionnaire to Assess Health-enhancing physical activity (the SQUASH Questionnaire)
- Completed at trial entry, 28 & 36 weeks gestation, and 4 months postpartum
- Evaluates time spent on different types of physical activity
  - Commuting, Leisure, Household, Work Related activities
- Activity assigned Metabolic Equivalent Task unit (METs)
  - Assessed as MET-minutes per week
  - Duration x frequency x MET intensity
Statistical Analyses

- Intention to treat basis
- Both adjusted and unadjusted analyses performed
- Linear mixed effects model
  - Treatment group, time point assessed and their interaction
  - Where treatment by time interaction significant, post hoc tests to assess the effect of treatment at each point
  - Where interaction was not significant, removed from model and main effect of treatment group estimated
Participant Flow

5,474 Eligible women approached to participate

3,262 Women declined

2,212 Women provided written consent and were randomised

3,262 Women declined

7 women withdrew consent to use data
25 women miscarriage before 20 weeks or termination of pregnancy
5 women suffered stillbirth after 20 weeks
1,067 live born infants
1 neonatal death
1 maternal death

945 women with valid Dietary Questionnaire
974 women with valid Physical Activity Questionnaire

1,108 (50.09%) Women randomised Lifestyle Advice

1,104 (49.91%) Women randomised Standard Care

928 women with valid Dietary Questionnaire
950 women with valid Physical Activity Questionnaire

3 women withdrew consent to use data
25 women miscarriage before 20 weeks or termination of pregnancy
5 women suffered stillbirth after 20 weeks
1,075 live born infants
4 neonatal deaths (3 lethal anomalies)
1 maternal death

7 women withdrew consent to use data
25 women miscarriage before 20 weeks or termination of pregnancy
5 women suffered stillbirth after 20 weeks
1,067 live born infants
1 neonatal death
1 maternal death
Baseline Characteristics

- Characteristics similar between Lifestyle Group and Standard Care Group for participants contributing data from
  - Dietary Questionnaires
  - Physical Activity Questionnaires
## Healthy Eating Index Scores

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Adjusted Treatment Effect</th>
<th>Adjusted P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Healthy Eating Index</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28 weeks</td>
<td>1.58 (0.89 to 2.27)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>36 weeks</td>
<td>1.77 (1.01 to 2.53)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Total Fruit</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28 weeks</td>
<td>0.20 (0.10 to 0.30)</td>
<td>0.0001</td>
</tr>
<tr>
<td>36 weeks</td>
<td>0.82 (0.13 to 0.35)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Whole Fruit</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28 weeks</td>
<td>0.19 (0.09 to 0.30)</td>
<td>0.0003</td>
</tr>
<tr>
<td>36 weeks</td>
<td>0.24 (0.12 to 0.35)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Dark Green &amp; Orange Vegetables</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28 weeks</td>
<td>0.10 (0.04 to 0.16)</td>
<td>0.0006</td>
</tr>
<tr>
<td>36 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 months postpartum</td>
<td></td>
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</tr>
</tbody>
</table>
## Food Groups, Macronutrients, Micronutrients & Glycaemic Load

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Adjusted Treatment Effect</th>
<th>Adjusted P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Energy (kJ)</td>
<td>178.60 (-26.56 to 383.77)</td>
<td>0.09</td>
</tr>
<tr>
<td>Fruit (number serves/day)</td>
<td>0.21 (0.08 to 0.35)</td>
<td>0.002</td>
</tr>
<tr>
<td>Vegetables (number serves/day)</td>
<td>0.47 (0.22 to 0.72)</td>
<td>0.0002</td>
</tr>
<tr>
<td>Fibre</td>
<td>1.55 (0.55 to 2.56)</td>
<td>0.002</td>
</tr>
<tr>
<td>% Energy Saturated Fat</td>
<td>-0.20 (-0.38 to -0.01)</td>
<td>0.04</td>
</tr>
<tr>
<td>Glycaemic Load</td>
<td>2.62 (-0.94 to 6.18)</td>
<td>0.15</td>
</tr>
<tr>
<td>Glycaemic Index</td>
<td>-0.22 (-0.48 to 0.04)</td>
<td>0.10</td>
</tr>
</tbody>
</table>

### Significant increase in consumption of potassium, vitamin A, vitamin C, and folate
### Physical Activity

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Adjusted Treatment Effect</th>
<th>Adjusted P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commuting Activity</td>
<td>11.83 (-26.75 to 50.42)</td>
<td>0.55</td>
</tr>
<tr>
<td>Leisure Activity</td>
<td>79.33 (-2.09 to 160.75)</td>
<td>0.06</td>
</tr>
<tr>
<td>Household Activity</td>
<td>265.60 (61.36 to 469.84)</td>
<td>0.01</td>
</tr>
<tr>
<td>Work Activity</td>
<td>80.85 (-163.12 to 324.83)</td>
<td>0.40</td>
</tr>
<tr>
<td>Total Activity</td>
<td>359.76 (74.87 to 644.65)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Change in total activity equivalent to 15-20 minutes brisk walking on most days of the week.
Women within the Lifestyle Advice Group further randomised
  – Access to a supervised walking group + Intervention sessions as previously described
  – Intervention sessions as previously described

Poor compliance
  – Despite initial consent to participate, only 14% of women attended a walking group session

No additional benefit of supervised walking group in increasing physical activity during pregnancy
Provision of an antenatal dietary and lifestyle intervention for women who are overweight or obese was associated with

- Increased consumption of fruits, vegetables, and dietary fibre
- Reduced percentage energy from saturated fats
- Increased consumption of Vitamins A and C, & folate
- Increased physical activity equivalent to 15-20 minutes brisk walking on most days

To summarise our findings...
What does this mean?
Are our findings of modest dietary changes consistent with the available RCT literature?
Limited available data reported from randomised interventions in pregnant women who are overweight or obese

Findings consistent with 3 small randomised trials reporting dietary changes (Guelinckx 2010; Wolff 2008; Rae 2000)

- Reduced consumption of saturated fat
- Effects evident in the absence of changes in total energy intake or gestational weight gain (Guelinckx 2010; Rae 2000)
Effect of dietary GI and GL on pregnancy outcomes uncertain

- Lower gestational weight gain
  - Walsh et al 2012 BMJ; Knudsen 2013 Br J Nutr
- Infant birth weight

Moses 2006 AJCN

Walsh 2012 BMJ; Knudsen 2013 Br J Nutr; Grant 2011 Diabe Res Clin Pract; Moses 2013 AJCN; Rhodes 2010 AJCN
Could the modest changes observed in maternal dietary intake have an effect on clinical outcomes?
• ROLO Randomised trial (Donnelly 2014 Pediatric Obesity)
  • Low GI diet associated with lower thigh circumference measure in neonates

• Project Viva Cohort (Donahue et al 2011 AJCN)
  • An association between higher maternal dietary polyunsaturated fatty acids and reduced childhood adiposity by skinfold thickness measurements

• Southampton Women’s Survey (Moon et al 2013 JCEM)
  • 263 mother-child pairs
  • Maternal dietary polyunsaturated fatty acids associated with childhood adiposity assessed at 4 and 6 years age by DEXA
Are our findings of modest changes in physical activity consistent with the available RCT literature?
• Little available data reported from randomised interventions in pregnant women who are overweight or obese

• Non-randomised cohorts
  • Physical activity declines across pregnancy among women of all BMI categories
  • Particularly evident among women who are overweight or obese

• Increased proportion of domestic & caregiving activities
  • 50% activity during pregnancy
  • 65% among pregnant women who are overweight or obese
    (Schmidt 2006 J Women’s Health; Chandonnet 2012 PLoS One; McParlin 2010 BMC)
Are our findings valid?
Which tools should be used?

- Self-completed questionnaires
  - 4 time points during pregnancy and the post-partum period
  - Sample size in excess of 2,000 pregnant women
  - More detailed assessment tools were not considered feasible
    - Dietary recall
    - Accelerometer or pedometer
  - Allow between group comparisons rather than “gold-standard” estimates
Which tools should be used?

• Dietary Assessment
  • Provision of “desirable” answers consistent with the intervention message
  • However, would also have anticipated reported changes in consumption of refined carbohydrates & sugar sweetened beverages, which was not observed

• Physical Activity Assessment
  • Use of pedometers and accelerometers not considered feasible
  • Poor estimation of upper body & stationary exercise
  • Poor estimation of low intensity activity
Pregnancy:
A teachable moment?
(Phelan 2010 Am J Obstet Gynecol)
Yes, but…

- Being pregnant provides a label
  - Safety in a broader environment where weight and weight gain are stigmatised

- Women more sensitive to barriers to change
  - Pregnancy complications, tiredness
  - Don’t like or feel like cooking or exercising
  - Lack of knowledge about healthy eating and physical activity
  - Lack of time
  - Lack of support
  - Higher cost of healthy eating
  - Lack of access to a safe place to exercise

(Sui et al 2013 Aust Medical J)
Our findings are consistent with the wider weight management literature from non-pregnant individuals...

Making lasting and significant change to diet and exercise patterns is hard!
Our findings provide evidence that high infant birth weight can be improved in the absence of changes in gestational weight gain.

Modest changes in dietary quality and physical activity are likely far more achievable from a public health perspective than are more restrictive approaches to limiting gestational weight gain.
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