Preliminary Findings of an Individually-Tailored Adaptive Intervention to Manage Perinatal Weight Gain

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The Pennsylvania State University
Symposium Objectives

- Describe individually-tailored, intensively adaptive intervention for managing perinatal weight gain
- Discuss preliminary findings from Study 1
- Highlight key lessons learned in preparation of Study 2
The Problem

• Majority of women enter pregnancy already overweight (OW 45%) or obese (OB 30%)
• GWG in excess of guidelines
  – OW 70%, OB 60%
• Elevates risks for maternal and fetal complications
  – GDM, preeclampsia, macrosomia
IOM GWG Guidelines

<table>
<thead>
<tr>
<th>Category</th>
<th>Prepreg BMI (kg/m²)</th>
<th>GWG Range</th>
<th>Rates of GWG 2nd-3rd TRI (M range in lbs/wk)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt; 19.8</td>
<td>28-40</td>
<td>1 (1-1.3)</td>
</tr>
<tr>
<td>Normal</td>
<td>19.9 – 24.9</td>
<td>25-35</td>
<td>1 (.08-1)</td>
</tr>
<tr>
<td>Overweight</td>
<td>25.0-29.9</td>
<td>15-25</td>
<td>0.6 (0.5-0.7)</td>
</tr>
<tr>
<td>Obese</td>
<td>&gt; 30.0</td>
<td>11-20</td>
<td>0.5 (0.4-0.6)</td>
</tr>
</tbody>
</table>

Very small amount of weight gain per week.
Managing GWG Should be Straight Forward?

- Review found 20% reduced risk of high GWG with diet only, exercise only, and diet + exercise
  - largely among normal weight women
- Not consistent in OW/OB women
  - OW/OB women have more trouble adhering to diet and exercise rec’s than NW women
  - limited effectiveness
  - recruitment & retention

(Muktabhant et al., 2015)
(Streuling et al., 2011; Sui et al., 2012; Choi et al., 2013)
• **Aim 1:** Establish feasibility of individually-tailored, intensively adaptive intervention for managing GWG in OW/OBPW (2 studies)

• **Aim 2:** Use data collected from Aim 1 and control systems engineering to build dynamical model
  – adapt dosages and characterize effects of energy balance and planned/self-regulatory behaviors (using m-health tools) on GWG

• Use model to develop an optimized intervention
  – as effective and efficient as possible
Studies

• Study 1: Feasibility
  – delivering components/dosages
  – self-monitoring with m-Health tools
  – measurement
  
  – Included:
    • 28 OW/OB pregnant women
    • randomized to 7 dosages over 4 wk
    • post individual interviews for user acceptability

• Study 2: Proof of Concept
  – implement criterion rule
  – fully adaptive intervention
  – intensive longitudinal data

  – Will include:
    • 30 OW/OB pregnant women
    • randomization to INT vs CON from ~8-12 wk-37 wk gestation
    • biomarkers for maternal stress; fetal growth and infant birth wt*

Lead to:
Better simulation model
Inform necessary modifications (intervention/measurement protocols)

Result in:
Control systems engineering to build model
Develop optimized intervention to effectively/efficiently manage GWG
## Intervention Components

<table>
<thead>
<tr>
<th>Education</th>
<th>Goal-Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>• GWG/nutrition/EX guidelines</td>
<td>• Principles, implementation intentions</td>
</tr>
<tr>
<td>• GWG plotting</td>
<td>• Healthy eating/EX plans</td>
</tr>
<tr>
<td>• Energy density, portion size, etc.</td>
<td>• Problem-solving/weekly feedback</td>
</tr>
<tr>
<td>• EX benefits, safety, strategies</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Self-Monitoring</th>
<th>Active Learning</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Behaviors, feedback, overcoming barriers</td>
<td>• Healthy eating/EX sessions</td>
</tr>
</tbody>
</table>

Components: Evidence-based from model programs (DPP, Look AHEAD, past GWG interventions, and PI research on promoting healthy behaviors in pregnancy with the Theory of Planned Behavior (NIDDK 07586702).
Intensive Longitudinal Data

Baseline

- Weight, Height
- GWG Attitudes/Knowledge
- HE Behaviors, TPB, Cognitions
- EX Behaviors, TPB, Cognitions
- Self-Regulation Behaviors
- Sleep Behaviors
- Psychological Well-Being
- Socio-demographic

Study 2

- Body Composition (Bod Pod)
- Serum Blood Biomarkers
- Cortisol (Urine)
- Mobile Metabolism/RMR

Intervention Dosage

Daily: Aria Scale, Jawbone/Actigraph
Weekly: MFP, Self-Report Measures

Follow-up

Weight, Height
GWG Attitudes/Knowledge
HE Behaviors, TPB, Cognitions
EX Behaviors, TPB, Cognitions
Self-Regulation Behaviors
Sleep Behaviors
Psychological Well-Being
Socio-demographic

Study 2

- Weekly: Cortisol, Perceived Stress, RMR
- 4-6 Weeks: Fetal Growth/Abnormalities

Study 2

- Body Composition (Bod Pod)
- Serum Blood Biomarkers
- Cortisol (Urine)
- Mobile Metabolism/RMR
Healthy Mom Zone Study 1

Preliminary Findings
Study 1: Feasibility of Dosages

Assessments
Baseline (week 1)
Intervention Dosage (weeks 2-5)
Follow-up (week 6)

Daily: Aria Scale, Jawbone/Actigraph
Weekly: MFP, Self-Report Measures

Dosage 1
Education
Self-Monitoring
Food Scale
Goal-Setting
HE/EX Plans
HE Demo’s

Dosage 2
Education
Self-Monitoring
Food Scale
Goal-Setting
HE/EX Plans
HE Demo’s
EX Session

Dosage 3
Education
Self-Monitoring
Food Scale
Goal-Setting
HE/EX Plans
HE Demo’s
EX Session
Self-Monitoring Feedback

Dosage 4
Education
Self-Monitoring
Food Scale
Goal-Setting
HE/EX Plans
HE Demo’s
EX Session
Self-Monitoring Feedback
Meal Replacement

Dosage 5
Education
Self-Monitoring
Food Scale
Goal-Setting
HE/EX Plans
HE Demo’s
EX Session
Self-Monitoring Feedback
Meal Replacement
2nd EX Session

Dosage 6
Education
Self-Monitoring
Food Scale
Goal-Setting
HE/EX Plans
HE Demo’s
EX Session
Self-Monitoring Feedback
Meal Replacement
2nd EX Session
3rd EX Session

Dosage 7
Education
Self-Monitoring
Food Scale
Goal-Setting
HE/EX Plans
HE Demo’s
EX Session
Self-Monitoring Feedback
Meal Replacement
2nd EX Session
3rd EX Session

Assessments
Study 1: Results

Baseline (week 1)
- Assessment: Daily: Aria Scale, Jawbone/Actigraph
- Assessment: Weekly: MFP, Self-Report Measures

Intervention Dosage (weeks 2-5)
- Dosage 1: Education, Food Scale, Goal-Setting, HE/EX Plans
- Dosage 2: Education, Food Scale, Goal-Setting, HE/EX Plans
- Dosage 3: Education, Food Scale, Goal-Setting, HE/EX Plans
- Dosage 4: Education, Food Scale, Goal-Setting, HE/EX Plans
- Dosage 5: Education, Food Scale, Goal-Setting, HE/EX Plans
- Dosage 6: Education, Food Scale, Goal-Setting, HE/EX Plans
- Dosage 7: Education, Food Scale, Goal-Setting, HE/EX Plans

Follow-up (week 6)
- Assessment: Daily: Aria Scale, Jawbone/Actigraph
- Assessment: Weekly: MFP, Self-Report Measures

N = 28 Eligible, 22 completed dosage assignment
Study 1: Dosage Feasibility Results

**Baseline** (week 1)

**Intervention Dosage** (weeks 2-5)

**Follow-up** (week 6)

**Assessments**

Daily: Aria Scale, Jawbone/Actigraph
Weekly: MFP, Self-Report Measures

**Dosage 1**
- Education
- Self-Monitoring
- Food Scale
- Goal-Setting
- HE/EX Plans
- HE Demo’s

**Dosage 2**
- Education
- Self-Monitoring
- Food Scale
- Goal-Setting
- HE/EX Plans
- HE Demo’s EX Session

**Dosage 3**
- Education
- Self-Monitoring
- Food Scale
- Goal-Setting
- HE/EX Plans
- HE Demo’s EX Session Self-Monitoring Feedback

**Dosage 4**
- Education
- Self-Monitoring
- Food Scale
- Goal-Setting
- HE/EX Plans
- HE Demo’s EX Session Self-Monitoring Feedback Meal Replacmt

**Dosage 5**
- Education
- Self-Monitoring
- Food Scale
- Goal-Setting
- HE/EX Plans
- HE Demo’s EX Session Self-Monitoring Feedback Meal Replacmt 2nd EX Session

**Dosage 6**
- Education
- Self-Monitoring
- Food Scale
- Goal-Setting
- HE/EX Plans
- HE Demo’s EX Session Self-Monitoring Feedback Meal Replacmt 2nd EX Session 3rd EX Session

**Dosage 7**
- Education
- Self-Monitoring
- Food Scale
- Goal-Setting
- HE/EX Plans

*N* = 28 Eligible, 22 randomized, 18 completed
(2 pregnancy losses prior to randomization; 4 lost to follow-up after screening, 4 drop-outs)
<table>
<thead>
<tr>
<th>Wt Status</th>
<th>Age $M$ (SD)</th>
<th>Gest Wk Study Start* $M$ (SD)</th>
<th>Pre-Preg BMI* $M$ (SD)</th>
<th>Weight Study Start* $M$ (SD)</th>
<th>GWG Study Start $M$ (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OW $(n=12)$</td>
<td>29.5 (5.9)</td>
<td>18 (4.5)</td>
<td>26.8 (1.5)</td>
<td>173.2 (17.8)</td>
<td>10.8 (9.1)</td>
</tr>
<tr>
<td>OB $(n=6)$</td>
<td>29.3 (5.0)</td>
<td>13.3 (2.4)</td>
<td>33.5 (3.0)</td>
<td>210.8 (27.3)</td>
<td>5.9 (3.9)</td>
</tr>
</tbody>
</table>

* Significant group difference at $p < .01$; Variations in participant characteristics precludes individual dosage examination
Identified threshold of “too much intervention” between dosage 6 and 7
  – dropped 3rd on-site exercise session – integrated ‘at home’ sessions

Protocol modifications
  – revised screening protocol (e.g., wider BMI range, excluded smokers)
  – increased efforts to recruit women into study sooner (~6-8 weeks gestation)

Assessment Protocol
  – dropped Supertracker and ASA-24 – women greatly disliked
  – less than 5% missing data despite intensive data collection
Challenges, Solutions, and Lessons Learned in Preparation for Study 2
Retaining Participants Longitudinally

• Clinic OBGYNs encouraging patients to join study
• Used feedback from Study 1 interviews to improve retention and reduce burden
  – revised instructions and developed summary table (tasks & appt’s)
  – developed PPT and video demo’s for m-health tools
  – adjusted compensation
Recruit / Enter Study
10-12 weeks gestation

GWG evaluation

meet GWG goal at study entry get:
baseline intervention

GWG evaluation

meet GWG goal: stay the course

GWG evaluation

assess GWG in 4-week cycles through delivery

GWG evaluation

exceed GWG goal at study entry: step-up

exceed GWG goal: step-up

Decision rule = evaluate GWG; dosage maintained if meet GWG goal; dosage increased if exceed GWG goal. GWG also a tailoring variable.
Criterion Rule for Evaluating GWG

- Study 2: started recruitment sooner (~6-8 wk gestation)
- Include 2-wk acclimation period
  - reduce burden (adjust to ILD schedule of measures), concerns about EX
- Adapt up after acclimation as needed
Correspondence of Actigraph & Jawbone for estimating kcal (avg discrepancy over 4 weeks was 26 kcal)

BMI = 26.9 kg/m²
Age = 31
GA @baseline = 17 weeks

BMI = 25.2 kg/m²
Age = 36
GA @baseline = 17 weeks
Underreporting of Dietary Intake

- Energy intake back-calculation from the energy balance model
- Numerical approximation of derivative term using 2nd order centered difference:

\[ EI(k) = \frac{-W(k+2)+8W(k+1)-8W(k-1)+W(k-2)-12 \cdot TK_2 \cdot (PA(k)+RMR)}{12 \cdot TK_1} \]

- Also developed other approaches to EI estimation:
  - Semi-physical identification using batch data to estimate systematic underreporting of EI in the presence of noise despite missing data
  - Kalman filtering approach for real-time EI estimation

- The results obtained from these three approaches are observed to be comparable
## Degree of Underreporting in Study 1

<table>
<thead>
<tr>
<th>Subject</th>
<th>MFP</th>
<th>Back Calculated EI</th>
<th>IOM Guideline</th>
<th>% Underreporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2166</td>
<td>2518</td>
<td>3161</td>
<td>14.0%</td>
</tr>
<tr>
<td>2</td>
<td>2234</td>
<td>3003</td>
<td>3237</td>
<td>25.6%</td>
</tr>
<tr>
<td>3</td>
<td>2349</td>
<td>2963</td>
<td>3237</td>
<td>20.7%</td>
</tr>
<tr>
<td>4</td>
<td>1859</td>
<td>2701</td>
<td>3155</td>
<td>31.2%</td>
</tr>
<tr>
<td>5</td>
<td>2457</td>
<td>2777</td>
<td>3155</td>
<td>11.5%</td>
</tr>
<tr>
<td>6</td>
<td>2239</td>
<td>3886</td>
<td>3259</td>
<td>42.4%</td>
</tr>
<tr>
<td>7</td>
<td>2010</td>
<td>2115</td>
<td>2795</td>
<td>5.0%</td>
</tr>
<tr>
<td>8</td>
<td>2419</td>
<td>2953</td>
<td>3275</td>
<td>18.1%</td>
</tr>
<tr>
<td>9</td>
<td>1793</td>
<td>2515</td>
<td>3187</td>
<td>28.7%</td>
</tr>
<tr>
<td>10</td>
<td>1477</td>
<td>2945</td>
<td>3216</td>
<td>49.8%</td>
</tr>
<tr>
<td>11</td>
<td>1376</td>
<td>2543</td>
<td>3120</td>
<td>45.9%</td>
</tr>
<tr>
<td>12</td>
<td>1534</td>
<td>3196</td>
<td>3214</td>
<td>52.0%</td>
</tr>
<tr>
<td>13</td>
<td>1204</td>
<td>2626</td>
<td>3223</td>
<td>54.2%</td>
</tr>
<tr>
<td>14</td>
<td>1793</td>
<td>2664</td>
<td>3155</td>
<td>32.7%</td>
</tr>
<tr>
<td>15</td>
<td>1378</td>
<td>1968</td>
<td>3109</td>
<td>30.0%</td>
</tr>
<tr>
<td>16</td>
<td>1358</td>
<td>2321</td>
<td>3181</td>
<td>41.5%</td>
</tr>
<tr>
<td>17</td>
<td>2126</td>
<td>2476</td>
<td>3184</td>
<td>14.1%</td>
</tr>
</tbody>
</table>

Values in kcal

- Range from 5-54%
- 100% underreported
Underreporting of Dietary Intake

Less Significant Underreporting

BMI = 25.2 kg/m²  
Age = 36  
GA @baseline = 17 weeks

More Significant Underreporting

BMI = 29.7 kg/m²  
Age = 34  
GA @baseline = 16 weeks

Add ACC reference
Calorie Goals

- IOM calories are based on energy needs for normal weight women
- Lack of guidance on EI for OW/OB women
- Explore use of calorie goal reduction (Vesco et al., 2012)

Vesco et al. (2012). Contemporary Clinical Trials, 33, 777-785.
Calorie Goals

Vesco et al. (2012). Contemporary Clinical Trials, 33, 777-785.
BMI = 27.4 kg/m²
Age = 28
GA @baseline = 22 weeks

BMI = 29.7 kg/m²
Age = 34
GA @baseline = 16 weeks
Safety Alerts for Study 2

- Weight loss
- Contraindications to EX
- Anemia
- Addition of Ultrasound protocol*
  - 2 participants had U/S flagged (fetus < 10%tile, low lying placenta)
  - immediate referral to OBGYN
  - obtain MD consent to continue participation
Conclusions & Next Steps

- Individually-tailored intervention intense dosages to manage GWG in OW/OB women appear feasible
  - women liked intervention components, enjoyed active learning activities
- Study 2 fully adaptive intervention
  - recruitment currently under way
- Goal to develop optimized (effective and efficient) intervention to manage GWG
Collaborative Team

- Dr. Jennifer S. Savage, Center for Childhood Obesity Research and Department of Nutritional Sciences, The Pennsylvania State University
- Dr. Daniel E. Rivera, Control Systems Engineering Laboratory, School for Engineering of Matter, Transport, and Energy, Arizona State University
- Drs. Linda Collins, Joshua Smyth, Barbara Rolls, Rick Legro, Jamey Pauli, Erica Rauff, Diana Thomas, Yueng Dong, Brandi Rollins, Katie Balantekin
- Abigail Pauley, Lindsey Hess, Allen Kunselman, Courtenay Devlin, Penghong Guo, Krista Leonard, Emily Hohman
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