

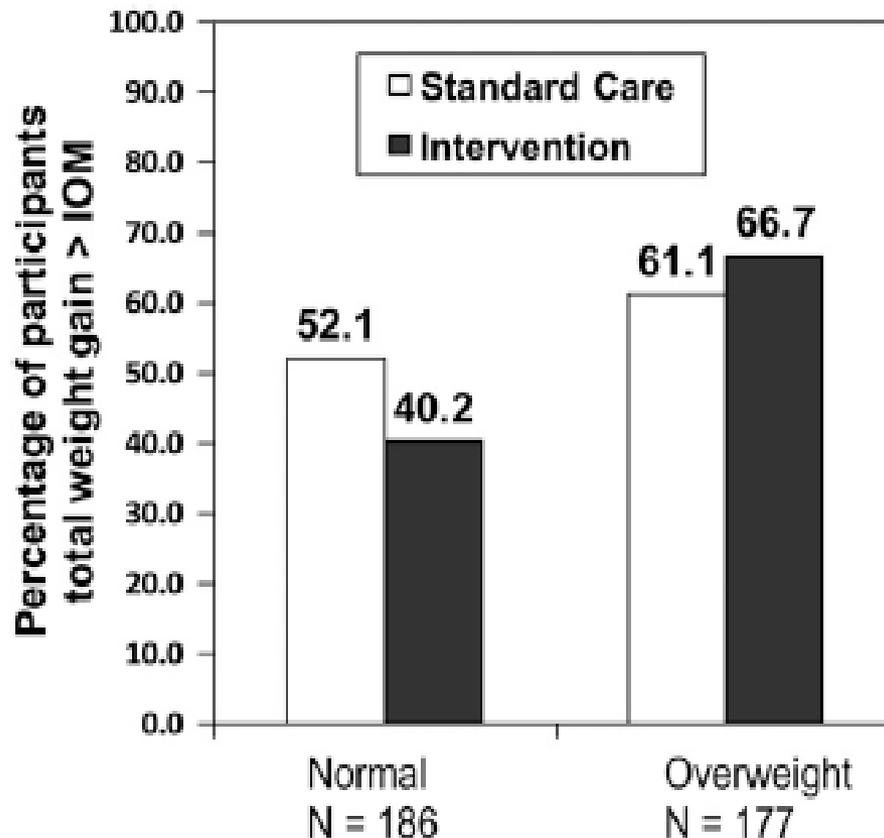
Objective 3

Evidence for safety and efficacy of
weight-directed interventions to
prevent excess weight gain during
pregnancy

Many behavioral interventions to control GWG fail in women who are overweight or obese

Randomized trial of a behavioral intervention to prevent excessive gestational weight gain: **the Fit for Delivery Study¹⁻⁴**

Suzanne Phelan, Maureen G Phipps, Barbara Abrams, Francine Darroch, Andrew Schaffner, and Rena R Wing



- 201 normal weight
- 200 overweight/obese
- Behavioral intervention (low intensity)

Example 2 – LIMIT Trial (Australia)

Antenatal lifestyle advice for women who are overweight or obese: LIMIT randomised trial

BMJ 2014;348:g1285 doi: 10.1136/bmj.g1285 (Published 10 February 2014)

- Multicenter study, Australia
- N=2,212 singleton pregnancies
 - BMI \geq 25 kg/m²
 - Usual care
 - Lifestyle intervention

Gestational weight gain (kg)	Lifestyle advice	Standard care
Mean (SD) total†	9.39 (5.74)	9.44 (5.77)
Mean (SD) average weekly (kg)†	0.45 (0.28)	0.45 (0.28)
Below recommendations	224/897 (25)	217/871 (25)
Within recommendations	293/897 (33)	286/871 (33)
Above recommendations	380/897 (42)	368/871 (42)

Did not reduce risk of delivering an infant >90th centile or improve maternal pregnancy and birth outcomes.

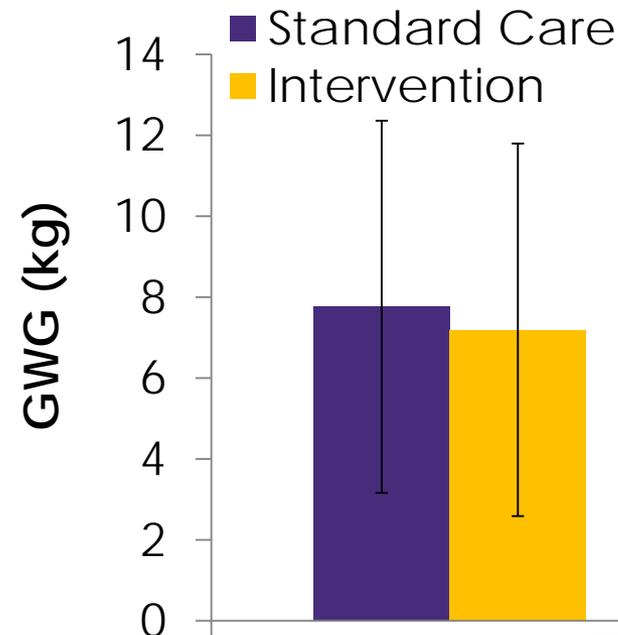
Example 3 – UpBeat Trial (UK)

Effect of a behavioural intervention in obese pregnant women (the UPBEAT study): a multicentre, randomised controlled trial

www.thelancet.com/diabetes-endocrinology Vol 3 October 2015

*Lucilla Poston, Ruth Bell, Helen Croker, Angela C Flynn, Keith M Godfrey, Louise Goff, Louise Hayes, Nina Khazaezadeh, Scott M Nelson, Eugene Oteng-Ntim, Dharmindra Pasupathy, Nashita Patel, Stephen C Robson, Jane Sandall, Thomas A B Sanders, Naveed Sattar, Paul T Seed, Jane Wardle, Melissa K Whitworth, Annette L Briley, on behalf of The UPBEAT Trial Consortium**

- N=1,555 singleton pregnancies
 - BMI ≥ 30 kg/m²
 - 15 weeks - <19 weeks gestation
 - Usual care (n=772)
 - Lifestyle intervention (n=783)
 - Attend 8 x weekly sessions
 - Pedometer, exercise DVD
 - Log book, recipes



Why are interventions for GWG failing?

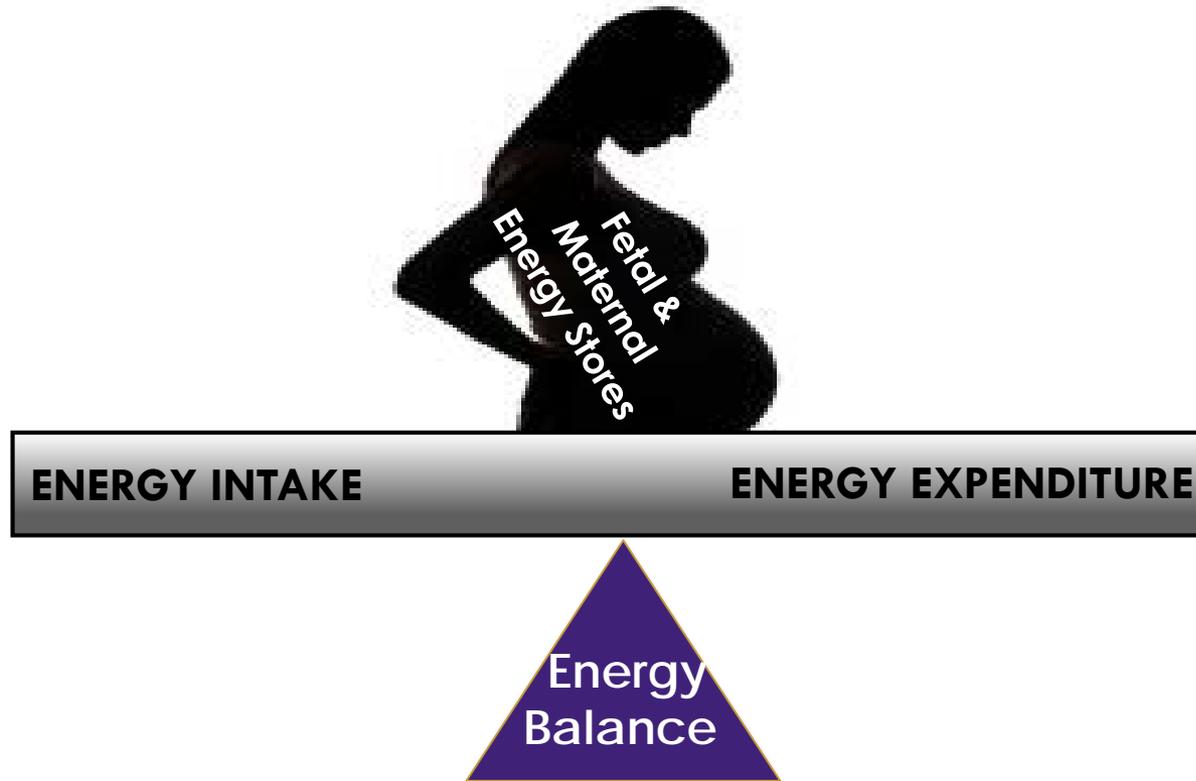
Pregnancy...is an ideal model for weight management

- Opportunity for a 24 week intervention (trimester 2-3)
- Frequent patient contacts throughout prenatal care continuum
 - Many studies start >20 weeks GA
 - Patients are already above IOM
 - Chasing a weight goal, little know-how, of how to do that
 - So no goals for dietary intake
 - Prenatal care is burdensome (In U.S. = 10-12 office visits)

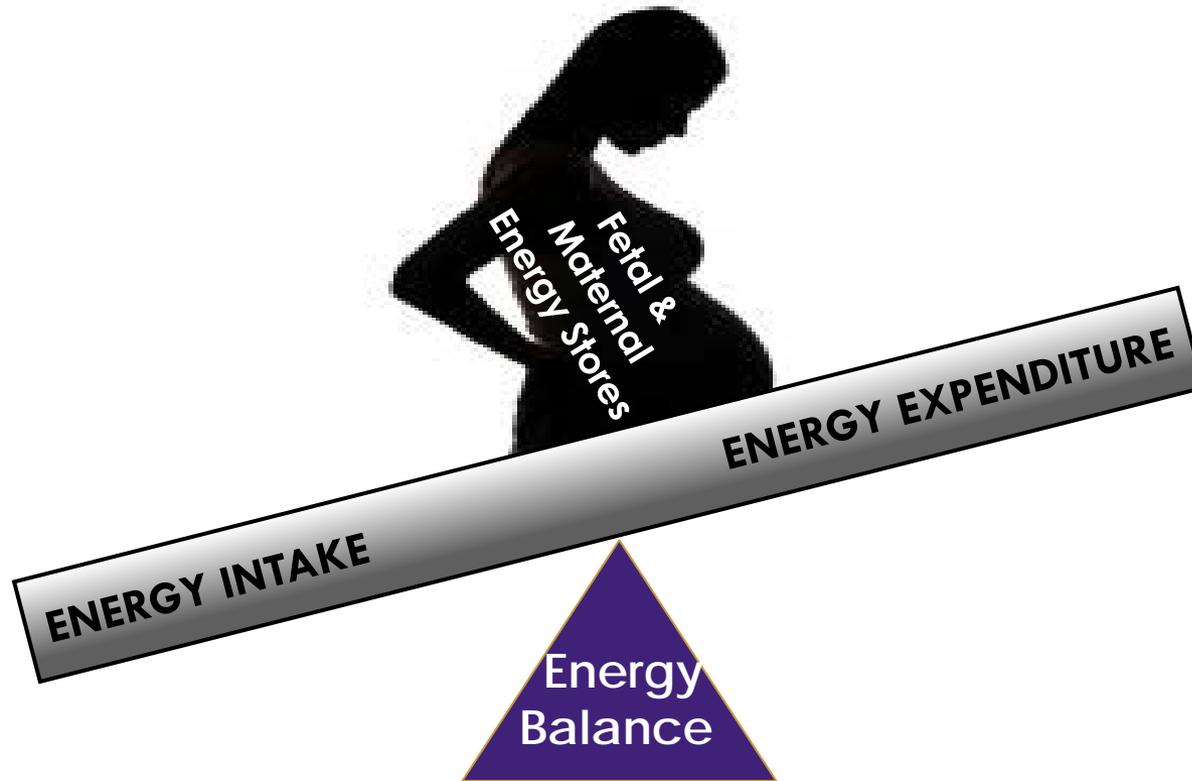
Goals needed for behaviors women can control –
dietary intake and physical activity

Little knowledge on what is driving gestational
weight gain!

What contributes to weight gain in pregnancy?



What contributes to weight gain in pregnancy?



What is the role of energy intake and energy expenditure for pregnancy weight gain?

$$\text{Energy Intake} = \text{Energy Expenditure} + \Delta \text{Energy Stores (FM/FFM)}$$

Energy requirements during pregnancy based on total energy expenditure and energy deposition¹⁻⁴

Nancy F Butte, William W Wong, Margarita S Treuth, Kenneth J Ellis, and E O'Brian Smith

63 pregnant women all recruited prior to pregnancy



Different components of energy expenditure

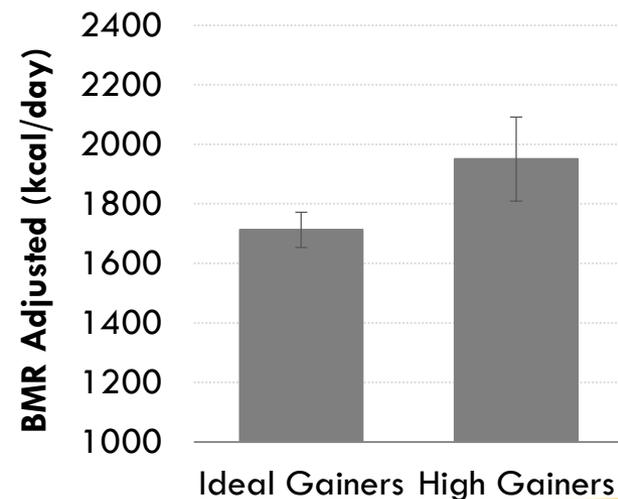
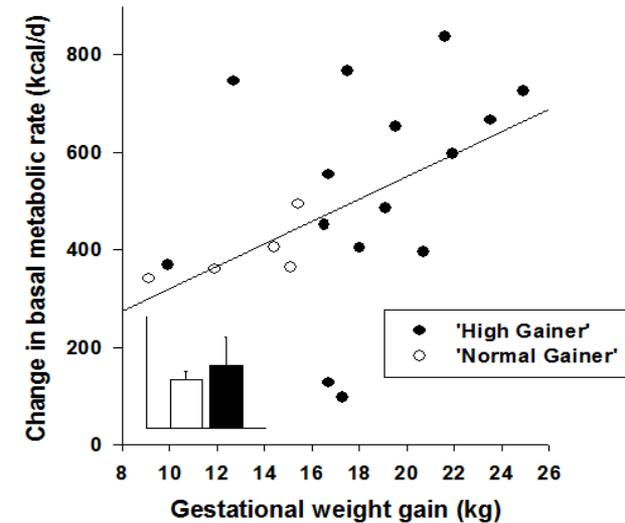
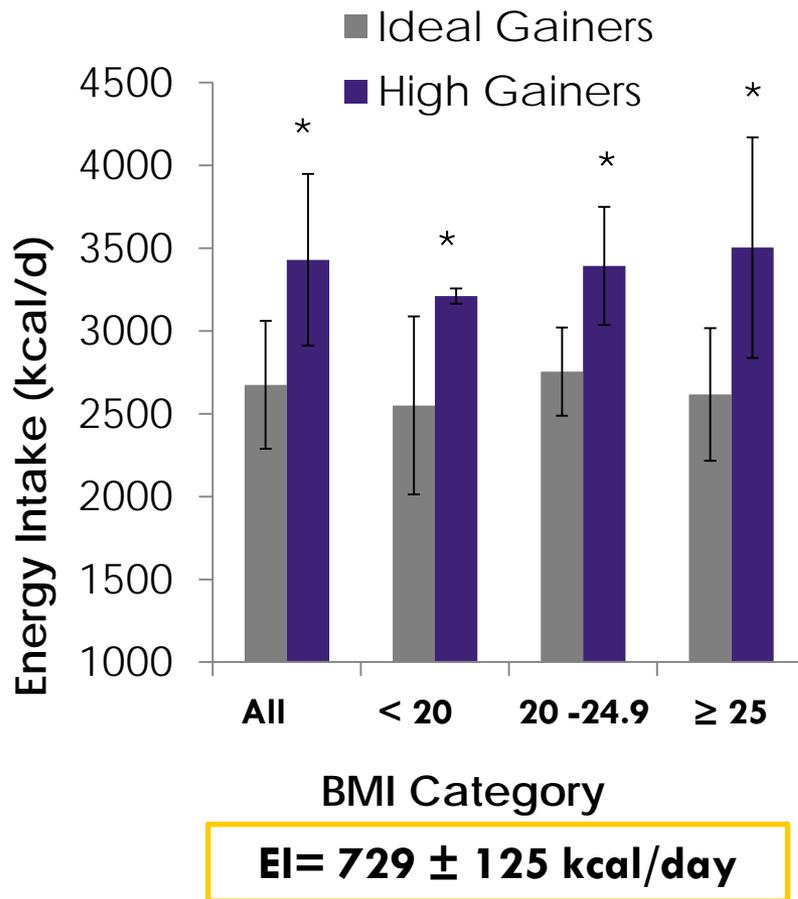
- Free-living energy expenditure by DLW
- Sedentary energy expenditure by room calorimetry (BMR)



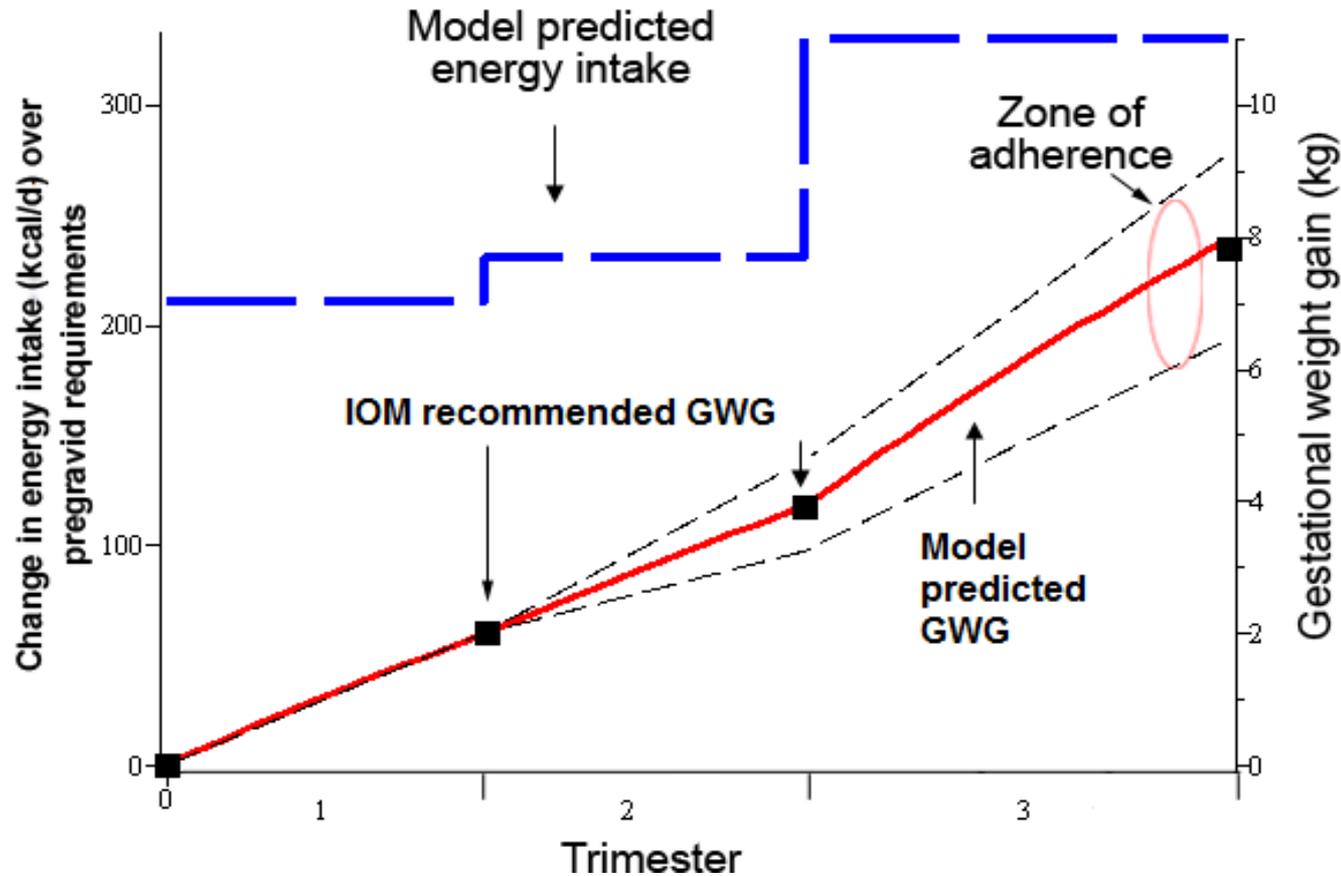
Weight gain in pregnancy is driven by EI and not EE

Gilmore, et al. Obstet Gynecol 2016

High Gainers = Above 2009 IOM guidelines | Normal Gainers = Within 2009 IOM guidelines



Can we tell pregnant women how much to eat to help reduce excess weight gain?



Mathematical Model for Maternal Weight Gain

$$ES = EI - EE$$

$$\underbrace{771 \frac{dFFM}{dt} + 9500 \frac{dFM}{dt}}_{ES} = \underbrace{(1 - g)(EI_0 + \Delta EI)}_{EI} - \underbrace{(15FFM + 1903)}_{EE}$$

$$FFM = FFM(0) + (TBW(W) - TBW(0)) + (TBP(W) - TBP(0))$$

$$= FFM(0) - TBW(0) - TBP(0) + TBW(W) + TBP(W)$$

$$= FFM(0) - TBW(0) - TBP(0) + 0.5W + 3.9 - 0.05W + 9.3$$

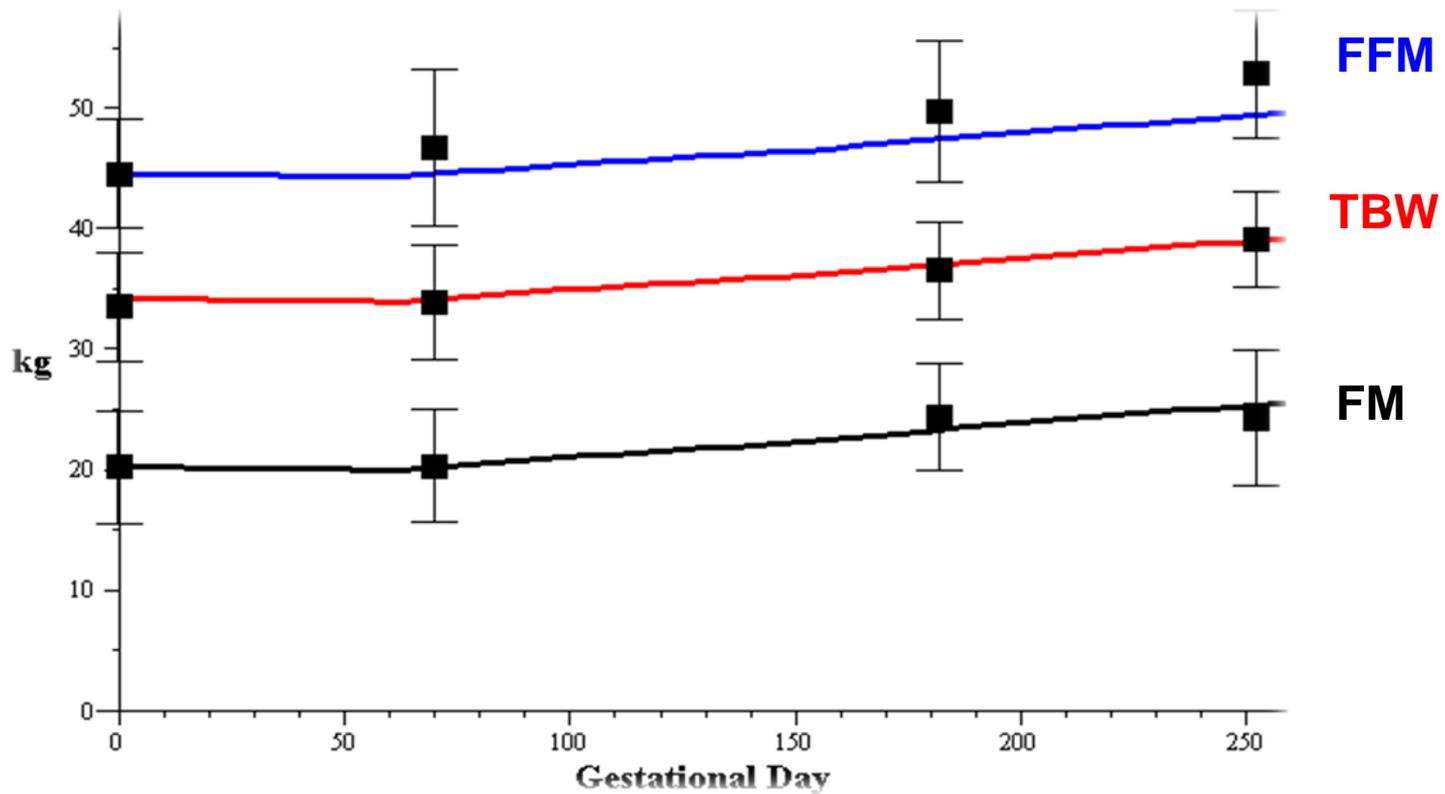
$$= FFM(0) - TBW(0) - TBP(0) + 0.5(FFM + FM) + 3.9 - 0.05(FFM + FM) + 9.3$$

$$TBW = 0.5W + 3.9 \quad TBP = \begin{cases} -0.05W + 9.3 & \text{if } W \leq 52\text{kg} \\ 0.1W + 1.3 & \text{if } 52 < W \leq 57.7 \text{ kg} \\ 0.08W + 3.1 & \text{if } W > 57.7 \text{ kg} \end{cases}$$

Model Validation

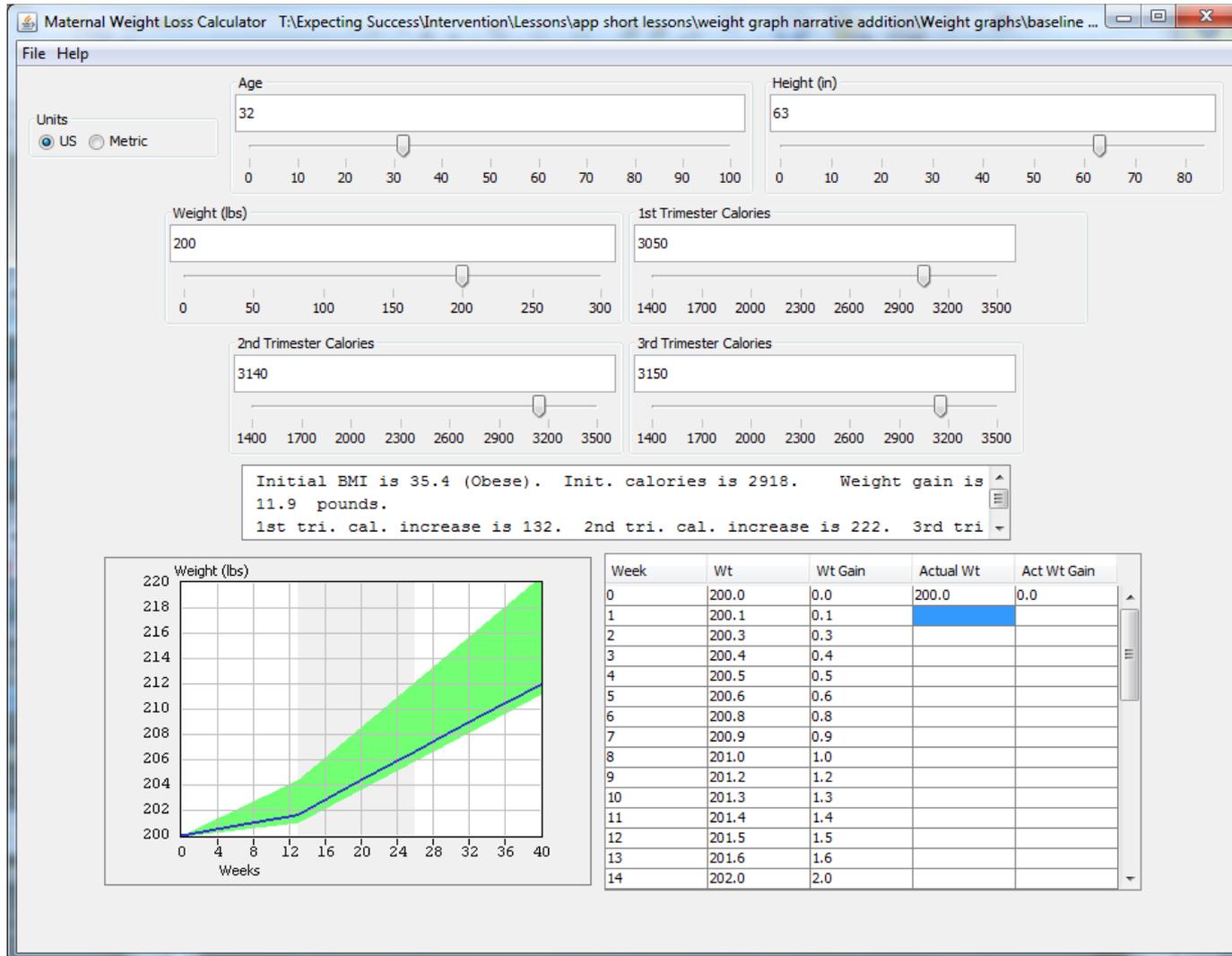
Kopp-Hoolihan LE, et. Al., Longitudinal assessment of energy balance in well-nourished, pregnant women.

Am J Clin Nutr. 1999 Apr;69(4):697-704.



Don't worry, we made it Physician/ Patient Friendly

<https://www.pbrc.edu/research-and-faculty/calculators/gestational-weight-gain/>



GWG interventions focused on Energy Intake are effective!

Efficacy of a Group-Based Dietary Intervention for Limiting Gestational Weight Gain among Obese Women: A Randomized Trial

Obesity (2014) **22**, 1989–1996.

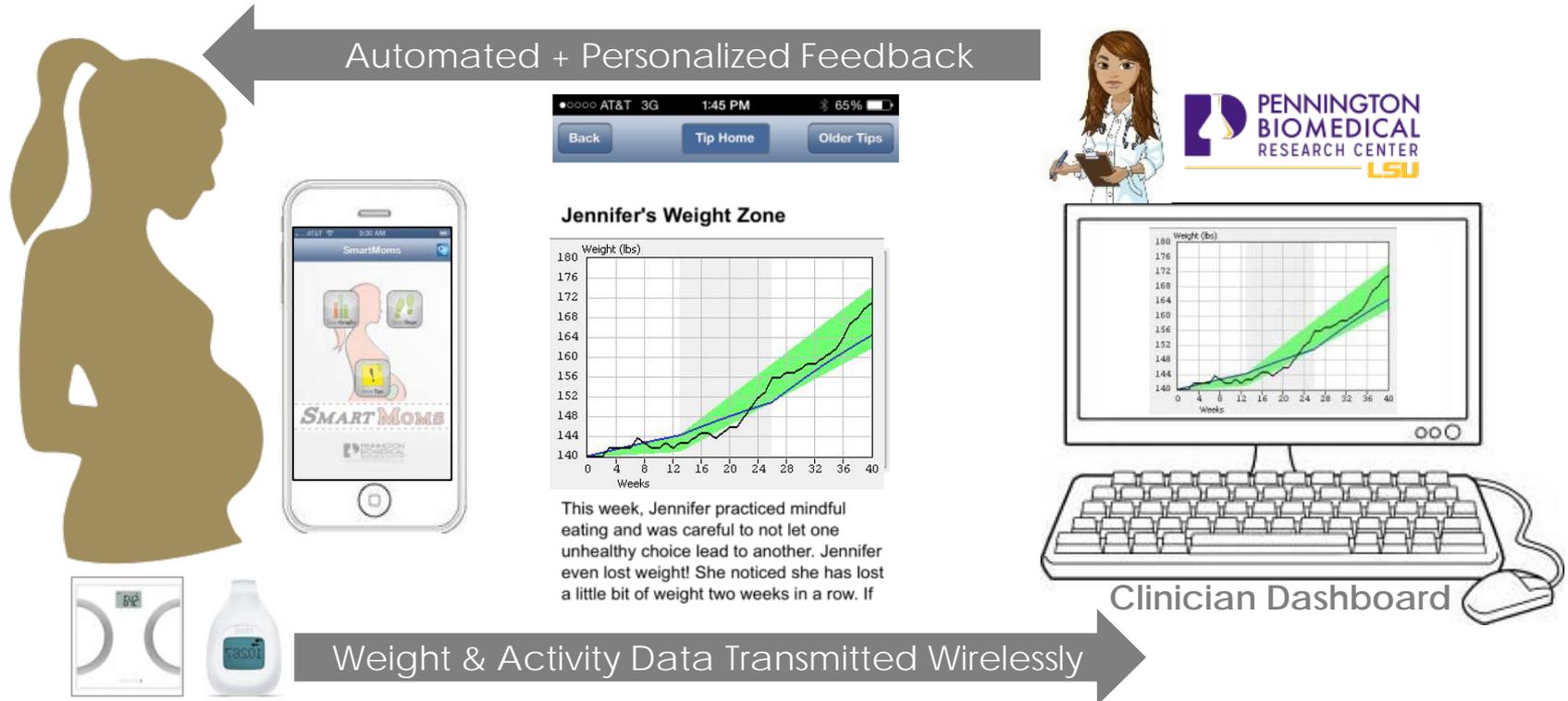
Kimberly K. Vesco^{1,2}, Njeri Karanja¹, Janet C. King³, Matthew W. Gillman⁴, Michael C. Leo¹, Nancy Perrin¹, Cindy T. McEvoy⁵, Cara L. Eckhardt⁶, K. Sabina Smith¹ and Victor J. Stevens¹

- Healthy Moms Trial, Kaiser Permanente NW
- N=118 singleton pregnancies, BMI ≥ 30 kg/m²
 - Usual care
 - Lifestyle intervention (maintain weight $\pm 3\%$ of randomization weight),
 - DASH diet, 30% calorie reduction below energy needs, 30 min/day of physical activity

	<u>Control</u>	<u>Intervention</u>
	Mean \pm SD or N (%)	Mean \pm SD or N (%)
2 weeks postpartum—randomization (kg)	1.2 \pm 5.6	-2.6 \pm 5.5
34 weeks gestation—randomization (kg)	8.4 \pm 4.7	5.0 \pm 4.1
Rate of weight gain (kg/week)	0.4 \pm 0.2	0.3 \pm 0.2
Rate of weight gain according to 2009 IOM guidelines for obese women		
Below (<0.18 kg/week)	7 (12%)	21 (38%)
Within (0.18 to 0.27 kg/week)	3 (5%)	10 (18%)
Above (>0.27 kg/week)	47 (82%)	24 (44%)

SmartMoms: Personalized management of body weight in pregnancy

The theoretical framework of SmartMoms



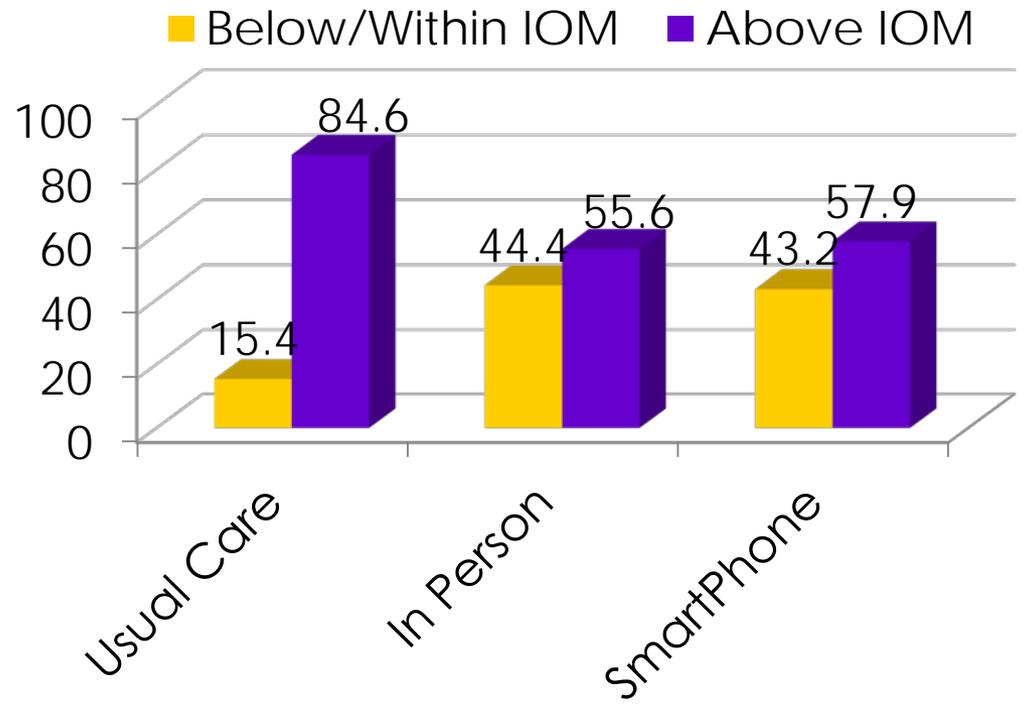
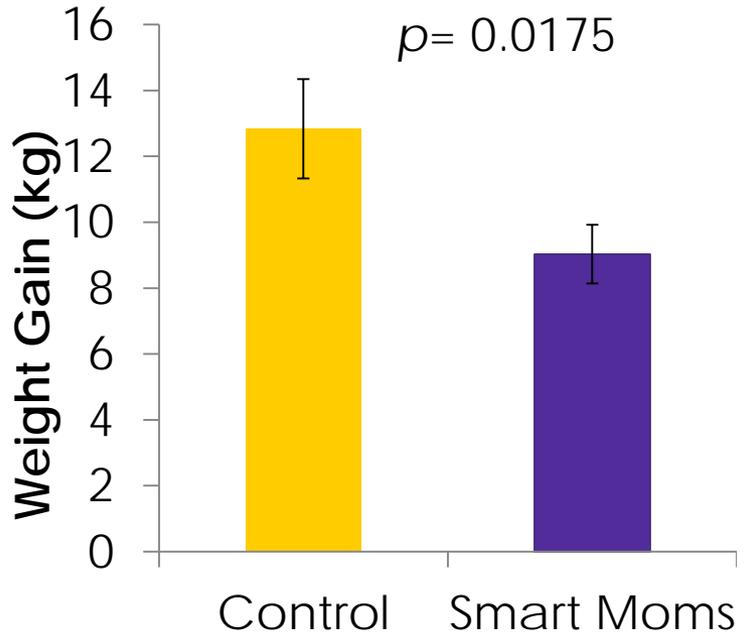
Adherence Metrics

1. Self-Monitoring of Weight
 - Frequency of weighing (# days of weight data / # days expected)
2. Self-Monitoring of Activity (steps)
 - Frequency of steps (# days of weight data / # days expected)
3. Session attendance
 - In Person Group only

	In Person	SmartPhone
Frequency of weighing		
Mean \pm sd	57.2 \pm 33.8	71.2 \pm 24.1
Median (min – max)	67.3 (0 - 95.4)	78.7 (0, 98.4)
Frequency of activity		
Mean \pm sd	44.5 \pm 33.3	72.5 \pm 29.0
Median (min – max)	51.9 (0 - 100)	88.0 (0, 100)
Attendance		
Mean \pm sd	78.1 \pm 39.0	100*
Median (min – max)	100 (0 - 100)	100*
TOTAL	60.8%	76.5%

SmartMoms significantly reduced total GWG

Total GWG = weight at 35-36w – weight at <13w



Group 1	Group 2	Difference (SE)	p-value
In-person	Usual Care	29.06 (0.15)	0.0296
Smartphone	Usual Care	26.72 (0.15)	0.0385



Economics of SmartMoms

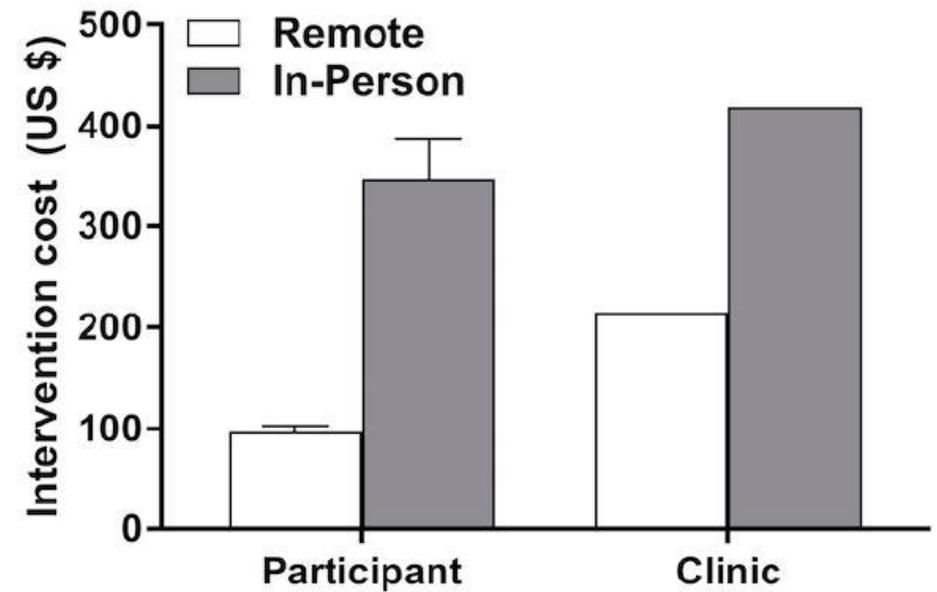
Participant Costs

- Average weekly income in East Baton Rouge Parish
- Actual travel time
- Time spent in sessions
- Time spent in activities
- Equipment cost

*Adjusted for individual adherence

Clinic Costs

- Average salary of interventionist
- Interventionist time
 - preparation
 - training
 - participant contacts
 - staff meetings
 - charting



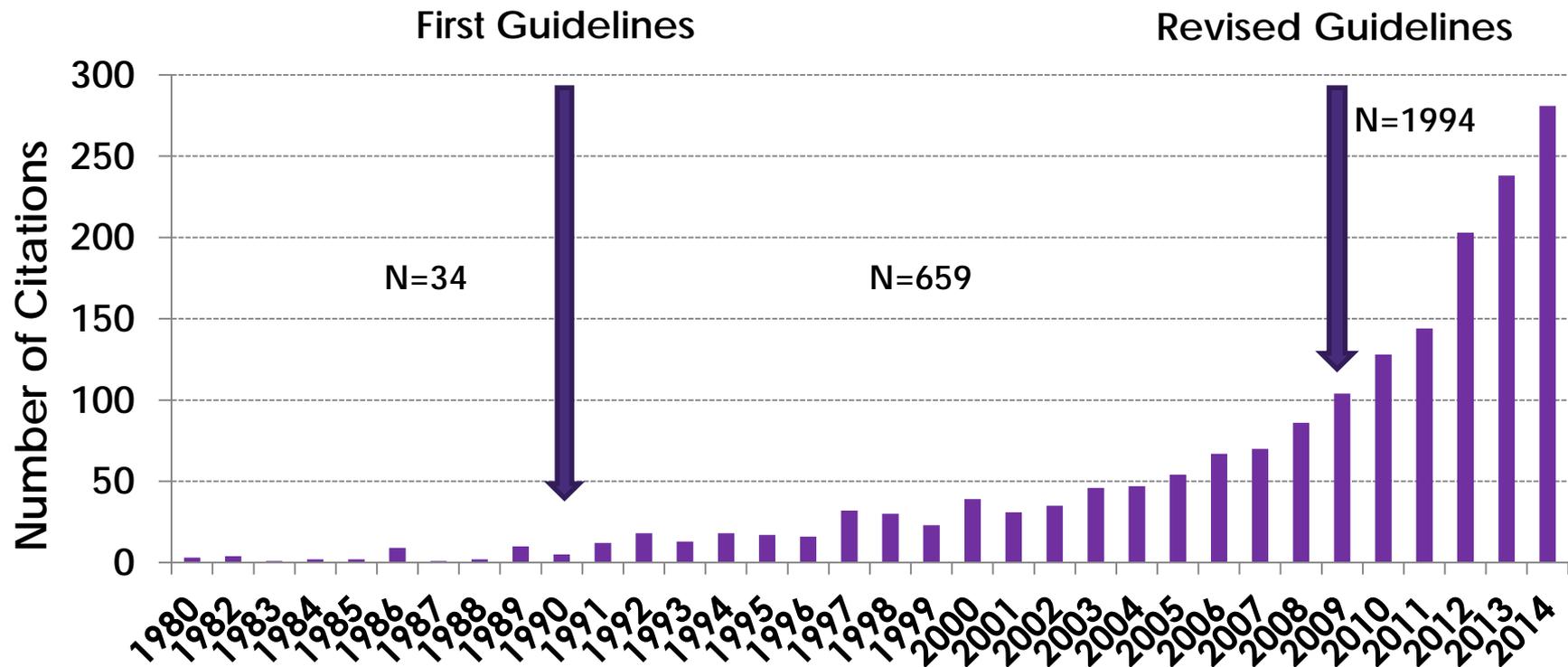
SmartMoms 2.5 cheaper for PARTICIPANTS

For CLINICS ~50% cheaper with the app
AND

30-50 new participants per month can be monitored per healthcare provider

GWG Interventions – an Area of Increased Attention

Pubmed search terms: Pregnancy + weight + intervention



Effect of diet and physical activity based interventions in pregnancy on gestational weight gain and pregnancy outcomes: meta-analysis of individual participant data from randomised trials

The International Weight Management in Pregnancy (i-WIP) Collaborative Group

33 RCT
N= 9,320

	# Studies	Intervention	Control	Mean Diff (95% CI)
Overall	33	10.1 (5.4)	10.8 (5.4)	-0.7 (-.92 to -.48)
Diet	4	10.2 (4.4)	11.0 (4.8)	-.72 (-1.5 to .04)
Physical Activity	15	9.8 (4.4)	10.8 (4.8)	-.73 (-1.1 to -.34)
Mixed	15	10.2 (6.0)	10.6 (5.9)	-.71 (-1.1 to -.31)

WHAT THIS STUDY ADDS

Diet and physical activity based interventions consistently reduce gestational weight gain across various subgroups of women categorised by age, parity, body mass index, ethnicity, and pre-existing medical condition

The reduction in odds of adverse maternal and offspring composite outcomes with diet and physical activity is not significant, and does not vary across various subgroups of women

Interventions significantly lower the odds of caesarean section and have no effect on offspring outcomes