

Women's Health Academic Centre

A pilot study to evaluate the effects of a dietary supplement with slow digesting-low GI (SD-LGI) carbohydrates in obese pregnant women using continuous glucose monitoring

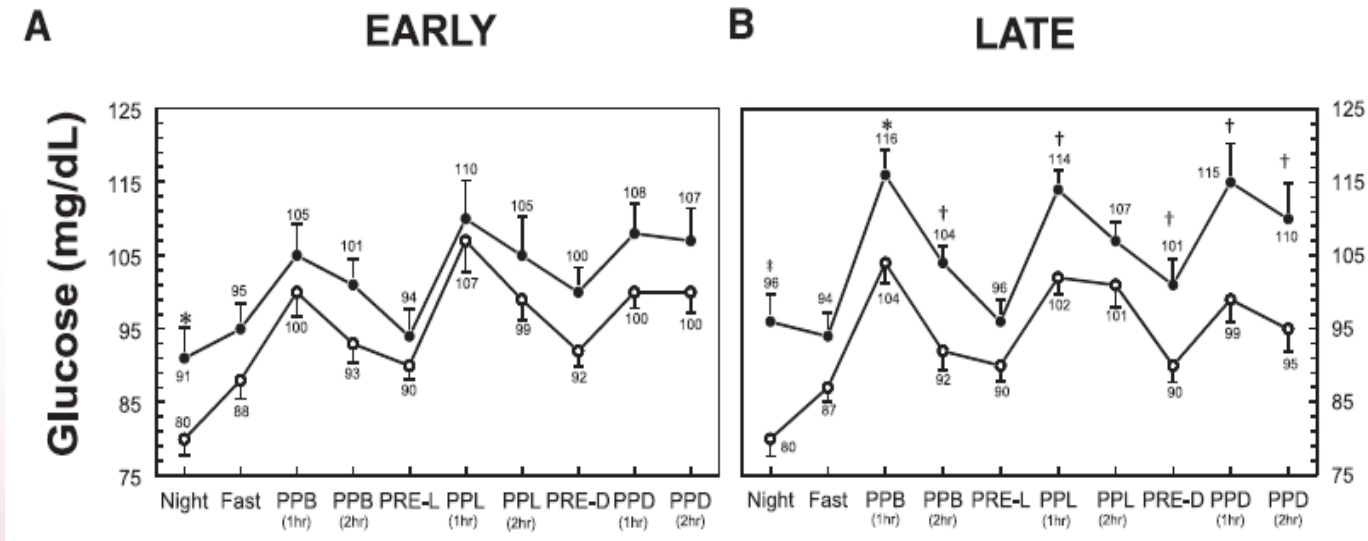
A collaboration between Abbott Nutrition and King's College London

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Maternal obesity is associated with abnormal glucose homeostasis

1. Greater glucose exposure in early/late gestation (CGMS & AUC) ¹
2. Greater post-prandial glucose response¹



3. Insulin resistance and dysregulation of lipid metabolism²
4. Macrosomia¹ & fetal adiposity^{1,3}

¹Harmon, *Diabetes Care*. 2011, ²Catalano, *AJOG*. 2011, ³Athukorala, *BMC Pregnancy & Childbirth*. 2010.

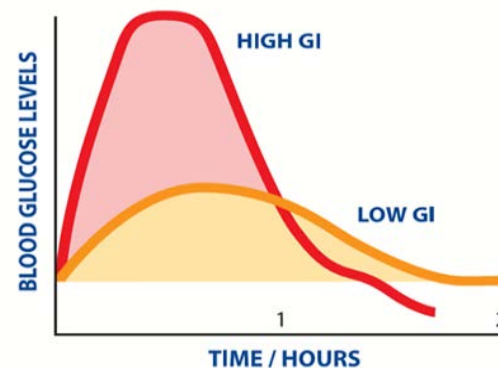
Could a low GI diet improve glucose homeostasis in pregnant women?

The Camden study (2004)⁴

- Glycemic index positively & significantly related to maternal HbA1c and plasma glucose concentration
- Women with LGI diet had < birth weight but increased risk of SGA

RCTs of high risk pregnant women

1. **ROLO**⁵: n=800
2. **LIMIT**⁶: n=2152
3. **PREGGIO**⁷: n=691



⁴ Scholl T, Am J Epidemiol. 2004 ⁵Walsh, BMJ, 2012, ⁶Dodd J BMJ 2014 , ⁷Moses et al, AJCN, 2014 & 2006

Aims

- To determine the glycaemic response following consumption of a slow-digesting low glycaemic index (SD-LGI) supplement in **obese** pregnant women
- To inform the design of a nutritional intervention RCT of dietary advice plus SD-LGI supplement in obese pregnant women at high risk of gestational diabetes:

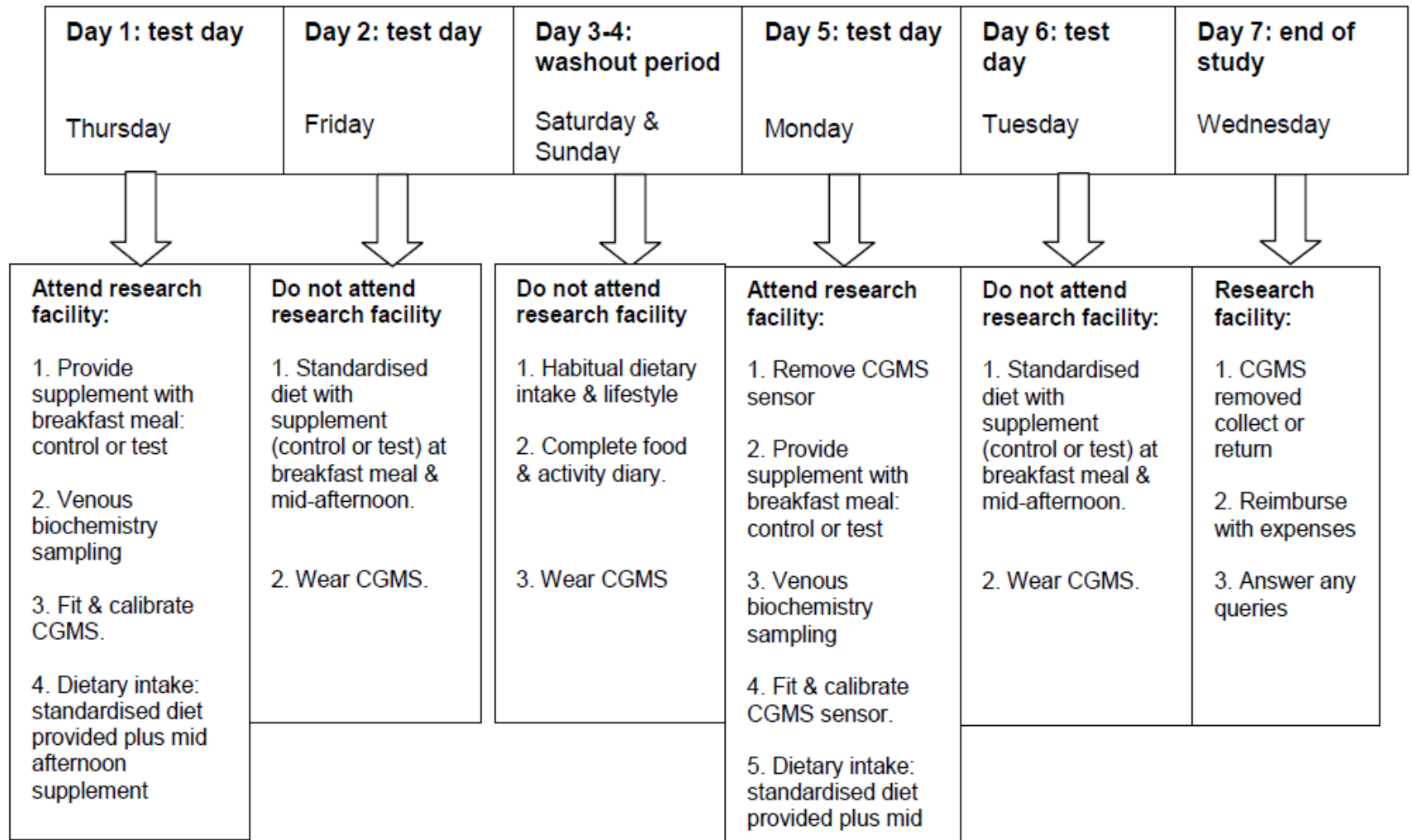
Nutritional Intervention during Gestation and Offspring Health Health study (NIGO)



Composition

Serving size 8oz	Test (12539RF)	Control (12551RF)
Calories (Kcal)	303	303
Total fat (g)	7	7
% calories from	20.8	20.8
Protein (g)	14	14
% calories from protein	18.5	18.5
Carbohydrate (CHO) (g)	46	46
% calories from CHO	60.7	60.7
• Rapid digesting (%)	8.4	100
• Slow digesting (%)	71.6	0
• Resistant starch (%)	16.3	0
• Indigestible fibre (%)	3.7	0

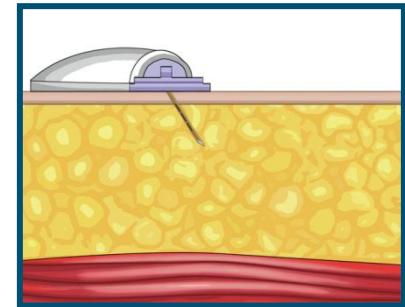
Participant flow chart



Continuous Glucose Monitoring Sensors

Abbott FreeStyle® Navigator One

- Subcutaneous electrochemical enzymatic sensor inserted under the skin (depth ~5mm)
- Connects via blue-tooth technology to receiver
- Measures glucose concentration of interstitial fluid
- Lag time: physiological delay 10-15 min between change in blood & interstitial glucose
- Calibration with CBG measurements at 5 time points: 1, 2, 10, 24 & 72-hrs
- In-built glucometer
- Worn up to 5 days



Data analysis

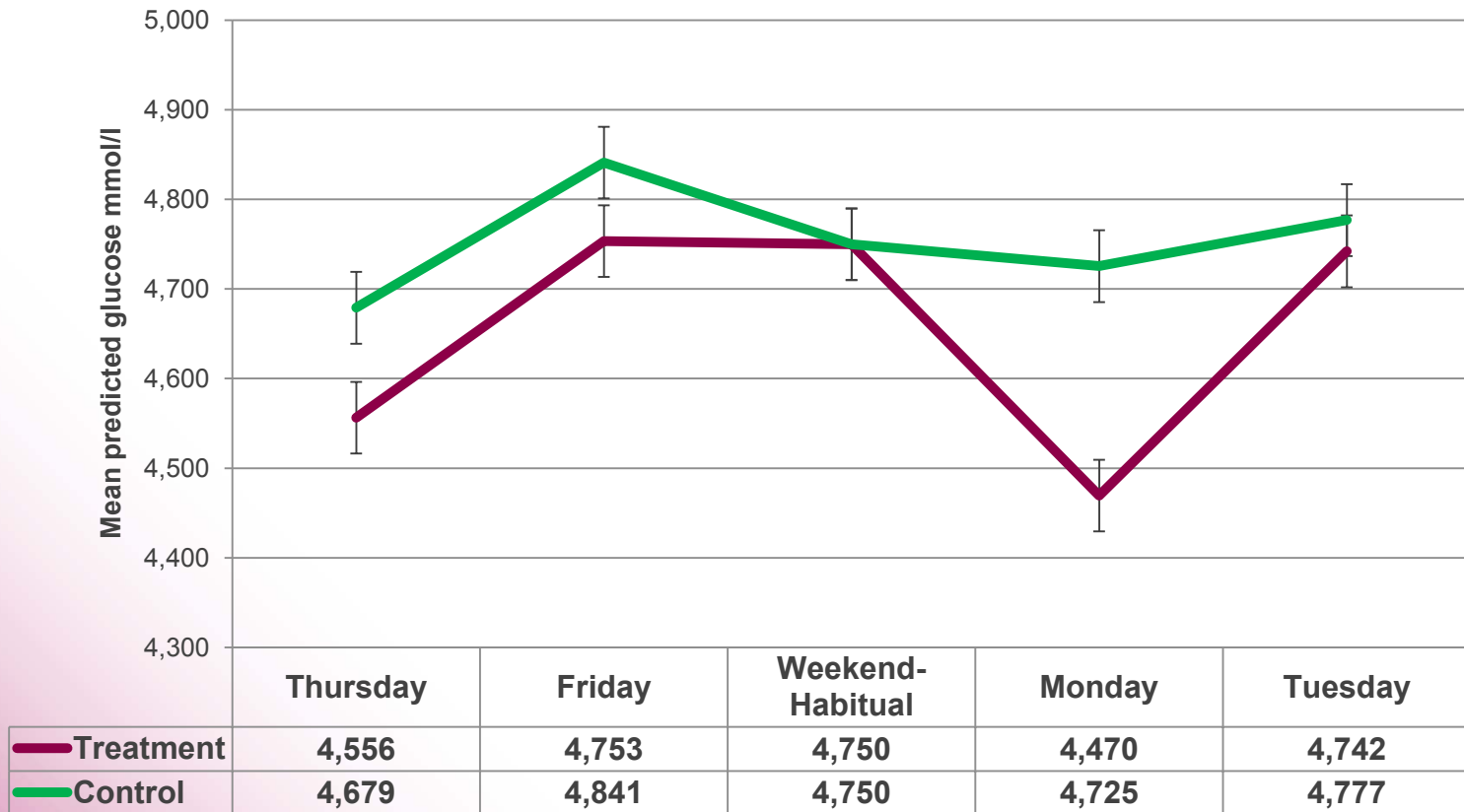
Criteria for “cleaning” CGMS data agreed between senior diabetes clinicians with experience of CGMS and expedited by 2 clinicians in parallel

Data points were treated as repeated measures and **mixed linear model** regression analysis was performed to generate predicted mean estimates for the test and control products.

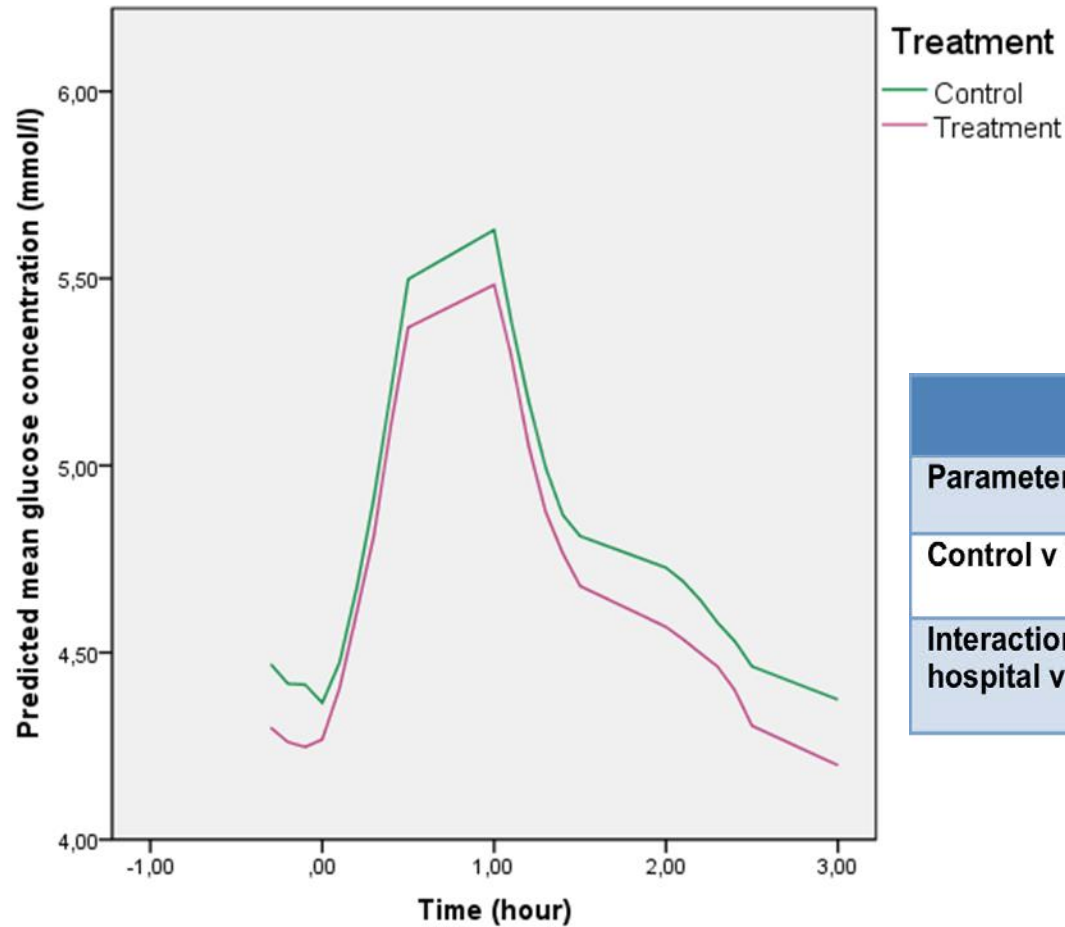
Results: Total Study Duration

Estimates of 24-hour means for treatment v control

Predicted mean and 95% CI by treatment



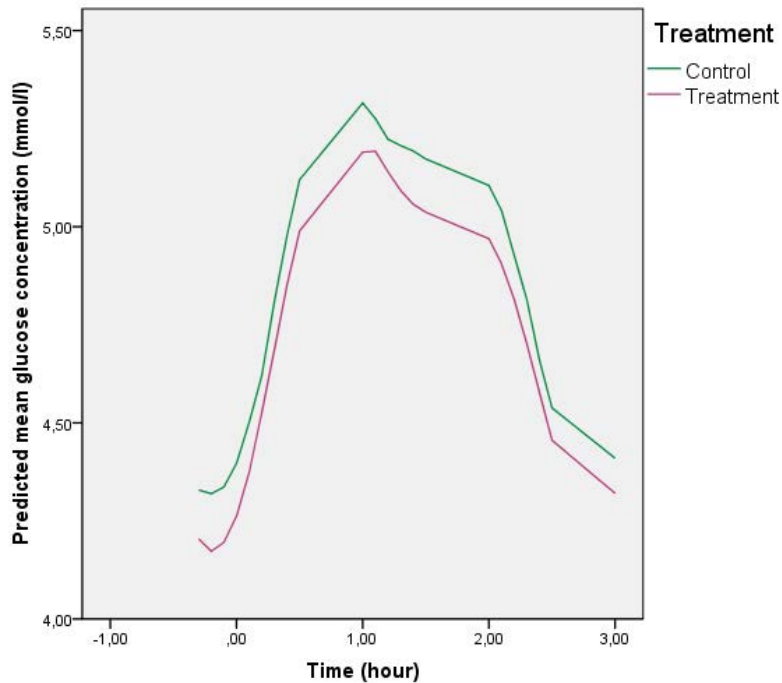
Post prandial glucose- Breakfast (180min)



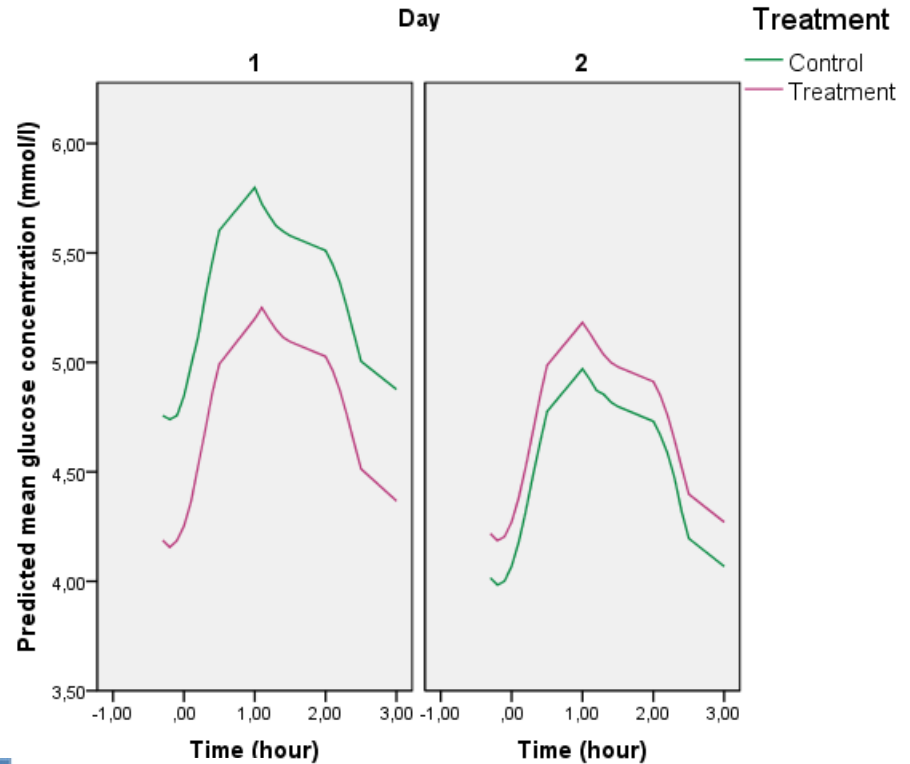
Estimates of Fixed Effects				
Parameter	Estimate	SE	P value	95% CI
Control v Treatment	0.09	0.04	0.03	0.01-0.18
Interaction hospital v home	0.18	0.07	0.007	0.05-0.31

Post prandial glucose- Lunch (180min)

a) Model-based estimations



b) Model-based estimations by day

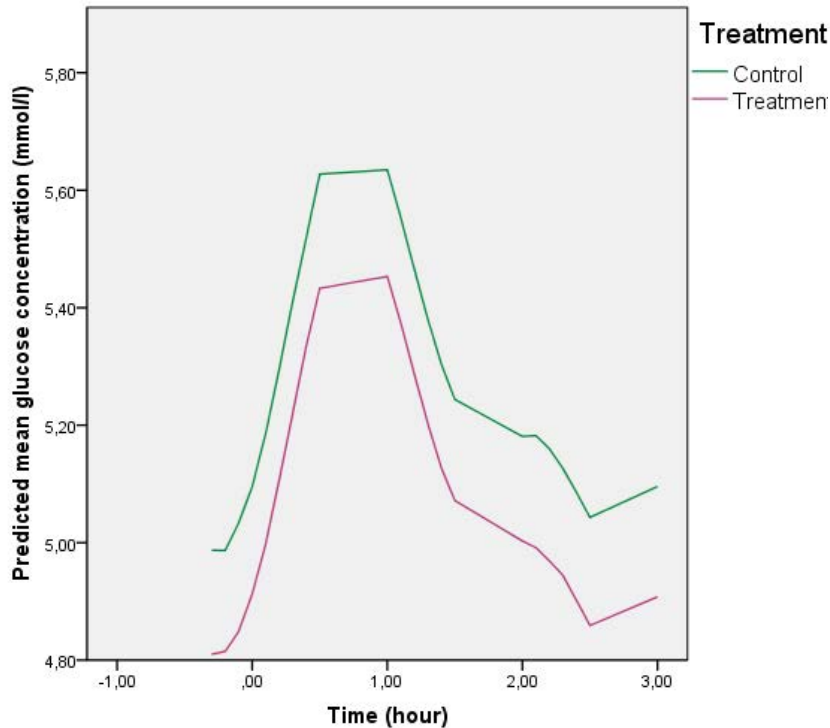


Estimates of Fixed Effects

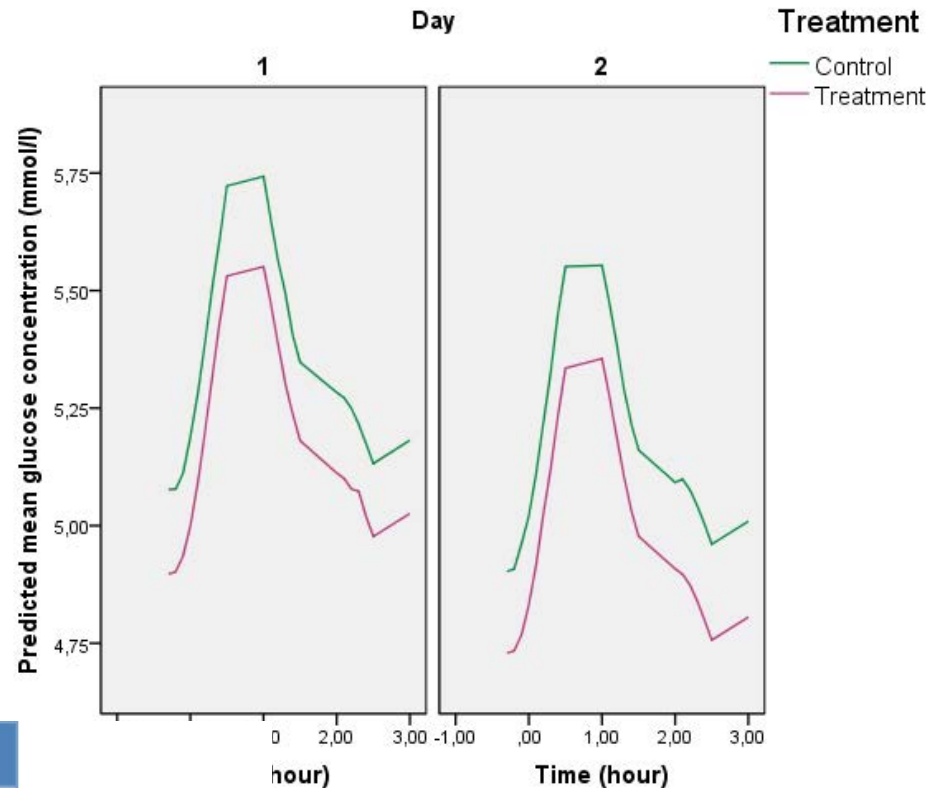
Parameter	Estimate	SE	P value	95% CI
Control v Treatment	-0.198	0.206	0.34	-0.62-0.22
Hospital v Home	0.055	0.210	0.80	-0.37-0.48

Post prandial glucose- Dinner (180min)

a) Model-based estimations



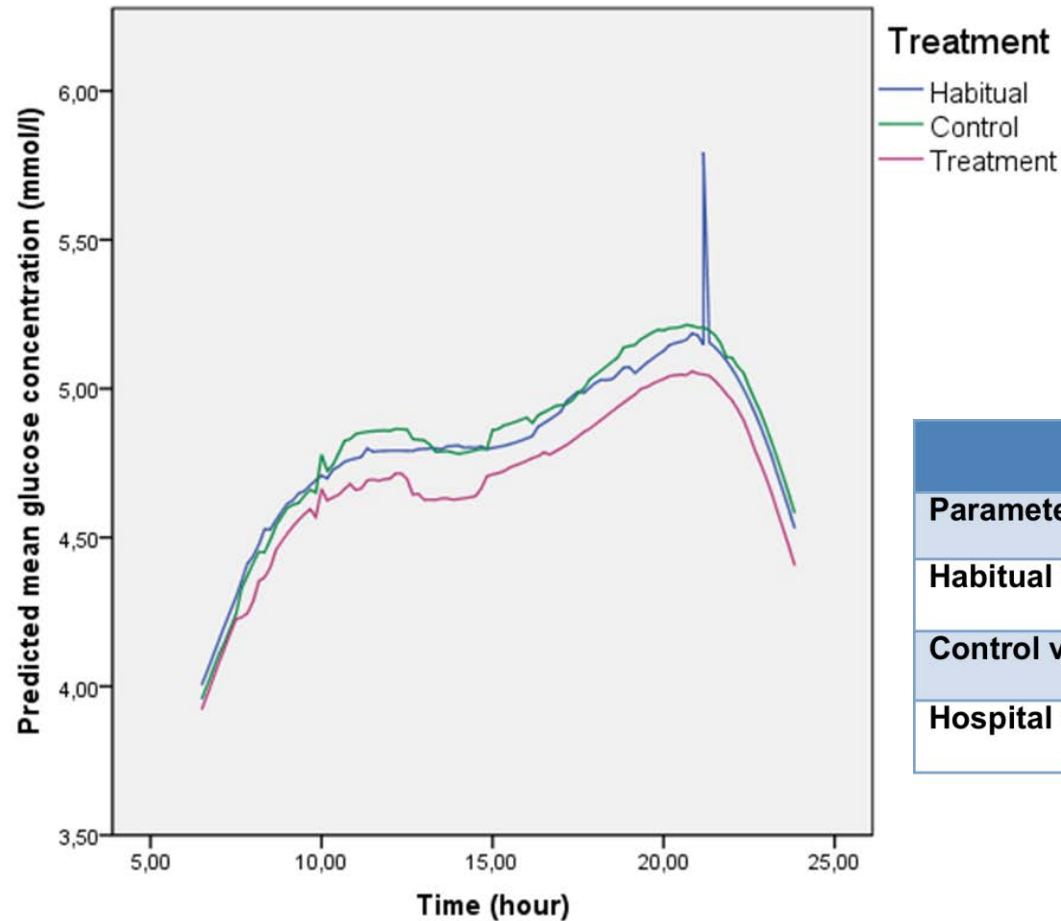
b) Model-based estimations by day



Estimates of Fixed Effects

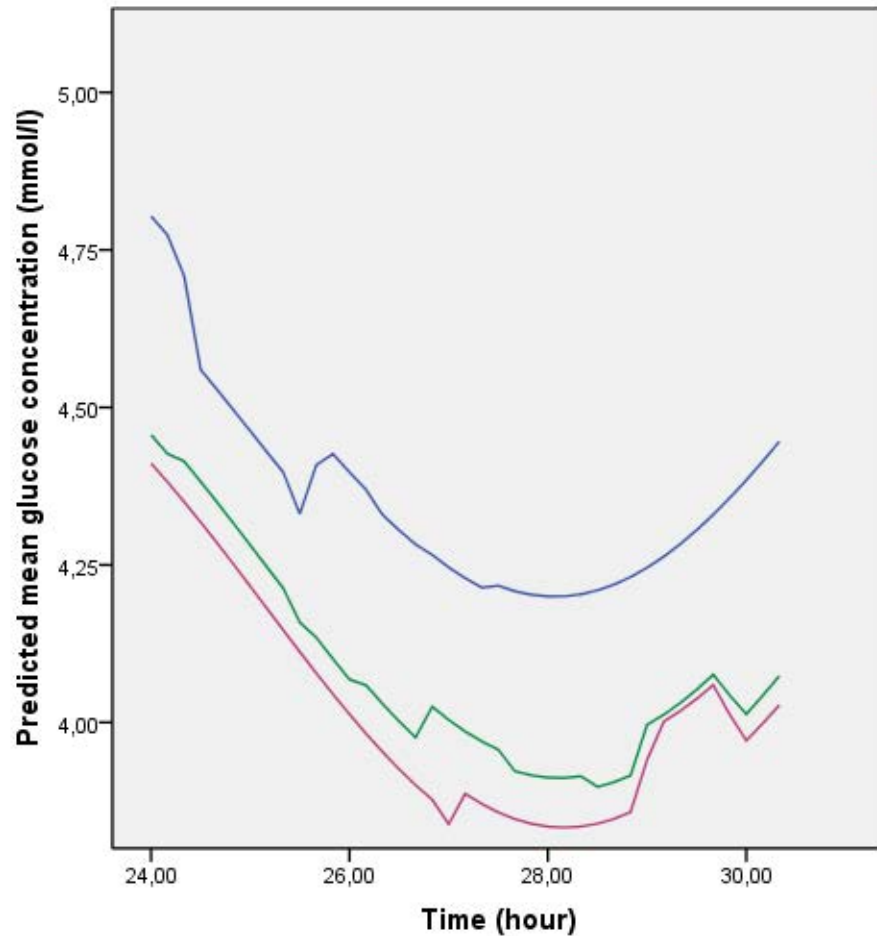
Parameter	Estimate	SE	P value	95% CI
Control v Treatment	-0.021	0.055	0.71	-0.13-0.09
Hospital v Home	-0.045	0.057	0.43	-0.16-0.07

Blood glucose measured by CGMS for daytime observations



Estimates of Fixed Effects				
Parameter	Estimate	SE	P value	95% CI
Habitual v Treatment	0.25	0.03	<0.001	0.19-0.31
Control v Treatment	0.26	0.04	<0.001	0.18-0.34
Hospital v Home	-0.02	0.03	0.54	-0.08-0.04

Night observations measured by CGMS (p29)



Estimates of Fixed Effects

Parameter	Estimate	SE	P value	95% CI
Habitual v Treatment	0.355	0.034	<0.001	0.29-0.42
Control v Treatment	0.050	0.030	0.09	-0.01-0.11

Study limitations

1. CGMS technical issues
3. High number of black Afro-Caribbean women
3. One woman likely to have overt T2DM therefore skewed results
4. Small sample size: to be validated in a larger pilot study
5. Duration

Summary of Results

In obese pregnant women, consumption of a SD-LGI carbohydrate drink:

1. Significant reduction in post prandial glycaemia at breakfast
2. Significant reduction in overall daytime glucose vs. control and habitual diet
3. Significant reduction in nocturnal glucose vs. habitual diet



The future: NIGO randomised controlled trial

- RCT of a structured dietary intervention with a SD-LGI nutritional supplement against a control of habitual diet
- Obese pregnant women (BMI $\geq 30\text{kg/m}^2$) at risk of GDM
- Primary outcome: 5% reduction in glucose AUC for intervention versus control
- Secondary outcome: neonatal adiposity



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Acknowledgments

Research team:

- **King's College London:** Rahat Maitland, Suzanne Barr, Eirini Platsa,
- **Abbott Granada:** Ricardo Rueda and Jose M Lopez
- **Abbott Ohio:** Barbara Marriage and Christina Sherry
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- **Diabetologist:** Helen Murphy (University of Cambridge)

Laboratory Support

- Carolyn Gill, Jo Gill (KCL)

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Questions?

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