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31 The ghana randomized air pollution and health study (GRAPHS): A cluster-randomized trial of clean cookstoves to improve obstetric outcomes

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OBJECTIVE: Low birth weight (LBW) accounts for 60-80% of all neonatal deaths worldwide, with over 95% of LBW infants born in developing countries. Prenatal cook smoke exposure from inefficient burning of biomass fuels (wood, hay) has been linked with LBW and stillbirth; almost half of the world's population uses these fuels. Policy efforts are underway to scale up clean cooking technologies globally but evidence that their introduction improves obstetric health is lacking. Our objective was to evaluate whether introducing clean cookstoves in pregnancy improves birth weight and other obstetric outcomes.

STUDY DESIGN: Pregnant women with singletons were enrolled from 35 Ghanaian community clusters into GRAPHS prior to 28 weeks and randomly assigned to cook with traditional fires, improved wood burning stoves (BioLite), or liquefied petroleum gas (LPG) stoves. Randomization to the three arms occurred at the cluster level with clusters balanced by sociodemographic and other key variables. Gestational age was established by ultrasound at enrolment. Weekly community-based field worker visits documented stove use compliance. Personal exposure to carbon monoxide was measured at repeated intervals. Newborn weight was measured with calibrated digital scales. Outcomes were compared by arm using multilevel regression models to account for clustering.

RESULTS: Of 1714 pregnant women screened from 09/13 to 06/15, 1414 were randomized to traditional fires (n=526), BioLite stoves (n=527), or LPG stoves (n=361). 78 participants miscarried or were lost to followup; 33 had stillbirths. In unadjusted intention-to-treat analysis for live births, birth weight did not differ for women using BioLite or LPG stoves compared to traditional fires (p=0.49 and 0.68)(Table). Secondary outcomes also did not significantly differ for either intervention versus control. Stillbirths were less frequent for LPG (6/346, 1.7%) compared with traditional fires (15/490, 3.1%) but did not reach significance (OR 0.6; 95%CI 0.2-1.5).

CONCLUSION: A strategy of providing improved cook stoves or fuels to individual pregnant women prior to 28 weeks does not improve mean birth weight or other obstetric outcomes in this rural African population. Clean energy may need to be provided to clusters or entire communities in order to achieve improvements in pregnancy health.

Obstetric outcomes for singleton live births in GRAPHS.

	Control arm	BioLite arm	LPG arm
	n=475	n=488	n=340
Primary Outcome			
Birth weight	2890 (± 490)	2920 (± 460)	2870 (± 490)
Secondary Outcomes			
Low birth weight	83 (17.7%)	77 (15.9%)	59 (17.4%)
Preterm birth	24 (5.1%)	17 (3.5%)	17 (5.0%)
Small for gestational age	99 (21.1%)	103 (21.3%)	75 (22.1%)

Left panel- traditional 3-stone fire; middle panel- BioLite stoves; right panel- LPG stove

32 Reduction of total labour length through the addition of parenteral dextrose solution in induction of labor in nulliparous: Results of DEXTRONS propective randomized controlled trial

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OBJECTIVE: Prolonged labour is a significant cause of maternal et foetal morbidity. Optimal uterine muscle function is critical to efficient active second stage of labour. The physiology of squelettal muscle suggests that glucose supplementation might improve muscle performance. The goal of our study was to provide reliable evidence as to whether IV glucose supplementation during labour induction in nulliparous women can reduce total duration of active labour.

STUDY DESIGN: We performed a prospective triple-blinded randomized-controlled trial investigating the use of parental IV of dextrose 5% with normal saline versus normal saline in 190 induced-nulliparous women. Inclusion criteria were monofoetal pregnancy at term with cephalic presentation and favourable cervix. After informed consent, patients were randomly assigned to receive either 250 mL/hour of IV dextrose 5% with normal saline or 250 mL/hour of normal saline for the whole duration of induction, labour and delivery. The primary outcome studied was the total length of active labour. Secondary outcomes include duration of second active stage of labour, mode of delivery and newborn APGAR score.

RESULTS: The duration of first and second stage of labour were significantly reduced in the dextrose group (441 versus 505 minutes,

$p = 0.045$). The proportion of patients delivered at 200 minutes was 19% in the dextrose group versus 8% in the normal saline group. The proportion of patients delivered at 450 minutes was 75% in the dextrose group versus 61% in the normal saline group. There were no difference in the rate of cesarean section and APGAR score.

CONCLUSION: Glucose supplementation significantly reduces the length of the first and second stages of labour without increasing the rate of complication in induced, nulliparous women. Given the low-cost and the safety of this intervention, glucose should be used as the default solute during labour.

33 Randomized control trial of IV acetaminophen for post cesarean delivery pain control

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OBJECTIVE: To determine if administration of IV acetaminophen following routine scheduled cesarean section delivery would decrease the need for narcotic medications to control post-operative pain.

STUDY DESIGN: This was an IRB approved, double-blind, placebo-controlled randomized trial, registered on clinicaltrials.gov (NCT02046382). Women scheduled to undergo routine cesarean section for singleton pregnancy at term were recruited for enrollment. Study patients were given all medications in a standardized manner receiving either acetaminophen 1000mg intravenous (IV) every 8 hours for 48 hours or saline (placebo) for a total of 6 doses. The pharmacy prepared IV acetaminophen and saline in identical administration bags labeled "study drug" to ensure blinding. The initial dose of "study drug" was given within 60 minutes of skin incision. Quantity of breakthrough and scheduled analgesic medications, self-reported pain on the Faces Pain Scale (0-10) before and after study drug administration, and demographics were extracted from the patients' charts. Power calculation determined that 45 patients per study arm were required to detect a 30% reduction in post-cesarean narcotic requirement with 80% power and a significance level of 0.05.

RESULTS: 133 patients were consented for the study. 29 were excluded and 104 patients were included with 57 of them receiving IV acetaminophen and 47 receiving placebo. There were no differences in baseline demographic characteristics including patient age, body mass index, gravidity, parity, ethnicity, comorbidities, or number of prior cesarean sections. There were no differences in estimated blood loss and length of surgery between groups. The total amount of narcotic medications consumed by patients receiving IV acetaminophen were significantly reduced when compared to the placebo group (47mg versus 65mg of oxycodone, p-value= 0.034). The total amount of ibuprofen used between groups was not different. There was no difference in the pain scores between the two groups before and after dose administration. There were no significant differences for reported medication side effects (nausea/emesis, respiratory depression, constipation) in either study arm.

CONCLUSION: IV acetaminophen in the post-operative time period for cesarean section surgery resulted in a significant decrease in the need for narcotic medications required for pain control.

34 Effect of a randomized controlled trial of an intensive medically supervised exercise program designed to improve maternal glucose control on gestational weight gain

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OBJECTIVE: To evaluate whether women with a body mass index (BMI) >29.9kg/m^2 enrolled in an intensive medically-supervised exercise intervention demonstrate a lower incidence of excessive gestational weight gain (GWG) compared to women undergoing routine care.

STUDY DESIGN: This is a prospective single-blinded randomized trial of obese women. Exclusion criteria were pre-existing diabetes mellitus, medications, no English, and BMI <30kg/m^2. Women were randomly assigned to: (1) routine prenatal care or (2) medically-supervised exercise intervention including three supervised exercise classes per week, invitation to a secret Facebook group to create a sense of community among participants and deliver healthy lifestyle advice. The study was adequately powered to detect a 7.2g/dL (0.4mmol/L) difference in mean fasting plasma glucose (FPG) levels on 2hOGTT. BMI and body composition were measured using bioelectrical impedance (Tanita MF 180CA) at the first prenatal visit and serially at 24-28 and 36 weeks gestation and at 6 weeks postpartum. Third trimester GWG was calculated at 36 weeks gestation. FPG was also measured. Excessive GWG was defined as >9kg for obese women as recommended by the Institute of Medicine (IOM). Independent t-test and chi-squared were used where appropriate.

RESULTS: Of 88 women randomized, 44 were assigned to intervention and 44 received routine care. Maternal age, race, parity, initial BMI were similar between groups (all P>0.05). There was no difference in mean 3rd trimester FPG between groups (p=0.66). The follow up rates were similar (95.5% v 85.7%; *P=0.09*) between groups. Anthropometric measurements are shown in Table 1. Excessive gestational weight gain was lower in the intervention group (22.2% v 43.2%; *P*<0.001).

CONCLUSION: Women with a BMI >29.9kg/m^2 enrolled in this medically-supervised exercise intervention program demonstrate a lower incidence of excessive gestational weight gain at 36 weeks' gestation. The same effect, however, is not seen on the mean GWG or mean fasting plasma glucose results. Clinicians should focus on improving pre-pregnancy BMI in this high risk population.

Table 1: Anthropometric changes during pregnancy and at 6 weeks postpartum

	Early pregnancy			24-28 weeks gestation			36 weeks gestation			6 wks postpartum		
	Control (n=44)	Intervention (n=44)	*P value*	Control (n=43)	Intervention (n=43)	*P value*	Control (n=42)	Intervention (n=36)	*P value*	Control (n=34)	Intervention (n=31)	*P value*
Anthropometrics												
Mean weight (kg)	95.8±15.8	93.9±14.8	*0.56*	101.1±15.4	98.8±13.7	*0.49*	103.6±15.6	101.1±13.9	*0.46*	96.7±16.2	91.9±14.1	*0.19*
Mean BMI (kg/m2)	35.0±5.2	34.7±4.7	*0.82*	36.8±5.2	36.5±4.5	*0.78*	37.8±5.3	37.4±4.7	*0.71*	35.4±5.9	34.0±4.7	*0.27*
Mean Fat %	41.7±4.0	41.8±4.0	*0.96*	42.6±3.8	42.4±3.3	*0.80*	42.2±3.9	41.6±3.4	*0.47*	40.8±4.3	40.2±4.0	*0.57*
Mean visceral fat level	8.5±2.9	8.5±2.4	*1.00*	9.2±2.8	9.1±2.1	*0.84*	9.5±2.8	9.2±2.1	*0.60*	8.6±3.1	8.1±2.3	*0.40*
Mean gestational weight gain Excessive weight gain (>9kg: IOM)	n/a	n/a	n/a	4.9±3.8	3.8±3.9	*0.19*	7.9±4.8 19 (43.2%)	6.2±6.0 8 (22.2%)	*0.15* <0.001	0.2±5.4	-1.6±1.2	*0.22*