

Study protocol

The Ibadan Pregnancy Cohort Study (IbPCS), a Prospective Cohort Study Protocol

*Adeoye I.A.^{1, 2}, Bamgboye E.A.¹ and Omigbodun A.O.³

¹Department of Epidemiology and Medical Statistics, Faculty of Public Health, College of Medicine, University of Ibadan, Ibadan, Nigeria ² Consortium for Advanced Research in Africa (CARTA), Nairobi, Kenya ³Department Obstetrics and Gynaecology, Faculty of Clinical Sciences, College of Medicine, University of Ibadan, Ibadan, Nigeria

ABSTRACT

Maternal obesity is a neglected public health challenge in Nigeria, even though it's associated with adverse metabolic, pregnancy, postpartum outcomes and future risk of non-communicable diseases. The Ibadan Pregnancy Cohort Study (IbPCS) investigates maternal obesity, lifestyle factors and the associated pregnancy and postpartum outcomes in Ibadan, Nigeria. IbPCS is an ongoing prospective cohort study that enrolled 1745 pregnant women at ≤ 20 weeks gestation at their first antenatal visit from four health facilities in Ibadan. Maternal body mass index (BMI) and lifestyle characteristics (Physical Activity - PA and Dietary Pattern) were assessed during enrollment using the pregnancy physical activity questionnaire and a qualitative food frequency questionnaire. The follow-up of participants was at 24 -28 weeks, third trimester, delivery and the postpartum period. Biomarkers (blood glucose and lipids) were assessed during the Oral Glucose Tolerance Test conducted between 24 – 28 weeks' gestation after an overnight fast. Baseline characteristics were: age (29.8±5.3 years), BMI (26.2±7.1kg/m2), primigravida (32.4%), married (94.2%), and tertiary level education (68.3%). This study will provide the preventive tools and lifestyle modification strategies required to mitigate the adverse effect of maternal obesity on maternal and child health and a future epidemic of cardiometabolic diseases in Nigeria.

Keywords: Maternal obesity, lifestyle characteristics, gestational diabetes mellitus, pregnancy and postpartum outcomes, Ibadan

*Author for correspondence: Email: adeoyeikeola@yahoo.com; Tel: +234 8094988108

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INTRODUCTION

Maternal morbidity and mortality are significant public health concerns in Nigeria, contributing to one of the highest maternal deaths worldwide, second to India (WHO, 2019). Nigeria accounts for 12% of global figures (35,000 maternal deaths) annually (WHO, 2019). In Nigeria, the maternal mortality ratio has dropped from 880 maternal deaths per 100,000 live births in 2000 to 578 maternal deaths per 100,000 live births in 2018 (NPC and ICF, 2019). The direct causes of maternal mortality include haemorrhage, anaemia, pregnancyinduced hypertension, infection and obstructed labour (Say et al., 2014). These had been the main focus of maternal mortality reduction efforts in Nigeria. The determinants of these adverse maternal outcomes in sub-Saharan Africa had been under-nutrition, infections (e.g. malaria, HIV), and micronutrient deficiencies in iron and folic acid; all are occurring within the context of a weak health system (Black et al., 2013, Tasneem et al., 2019).

The global epidemic of obesity, particularly among women of reproductive age, has made obesity during pregnancy a public health priority because of the associated pregnancy complications. Maternal obesity also increases the frequency of surgical interventions, the cost of treatment, especially the need for sophisticated equipment, prolongs hospital stay and neonatal admissions, and future risk of chronic diseases (Ma et al., 2016). Globally, there are an estimated 38.9 million overweight and obese pregnant women and 14.6 million obese pregnant women. Countries having the highest figures are India (4.3 million), China (4.28 million), Nigeria (2.13 million) and the USA (1.9 million). Of all these countries, Nigeria has had the highest rise in the prevalence rate (55.4%) of overweight and obese women over ten years (2005 - 2014) (Chen et al., 2018). Recent studies also corroborate the increase in maternal obesity in Nigeria (Ajen et al., 2014, John et al., 2015, Olavide et al., 2018). Hence, maternal obesity has become a new but neglected threat to maternal health in Nigeria.

Maternal obesity or obesity in pregnancy is defined as obesity in women at the start of pregnancy (measured by a prepregnancy body mass index \geq 30 kg/m2) (Simas *et al.*, 2011, Poston et al., 2016). Nutritional transition is responsible for the upsurge of obesity in low and middle-income countries (LMIC) (Popkin and Doak, 1998, Popkin, 2001, Prentice, 2006, Popkin et al., 2012). Nutritional transition is a lifestyle characterised by dietary changes from a traditional diet rich in grains, tubers, vegetables and fruits to a western diet characterised by refined carbohydrates, high sugar, salt and saturated fats and increased physical inactivity, sedentary occupations and livelihoods. However, lifestyle characteristics and drivers of maternal obesity have received very little attention, particularly in sub-Saharan Africa (Moore Simas et al., 2015). Researchers have noted that "identifying the modifiable risk factors of obesity will provide epidemiological tools fundamental to planning interventions with a positive public health impact" (Portela et al., 2015).

Maternal obesity can negatively affects glucose, lipids and amino-acid metabolism leading to a hostile metabolic environment characterised by insulin resistance, hyperglycaemia, hyperlipidaemia and gestational diabetes mellitus (GDM) (King, 2006, Nelson *et al.*, 2010, ADA, 2003, ADA, 2020). These metabolic dysfunctions can mediate the occurrence of pregnancy and postpartum complications, which have not been thoroughly examined among the Nigerian pregnant population. Additionally, gestational weight gain is a normal physiologic response to pregnancy needed to meet the baby's requirement for growth and development. Obese women can only tolerate a minimal gestational weight gain (GWG) (IOM, 2009). Maternal obesity, GDM and excess GWG provide extra metabolic fuels to the fetus, leading to perinatal complications like macrosomia and exerting postpartum effects like postpartum weight retention and postpartum dysglycaemia (Godfrey et al., 2017). These issues and how they connect have not been explored in Nigeria, where the maternal mortality ratio (MMR) is the second-highest worldwide. Understanding the lifestyle factors and outcomes of an upsurge of obesity among women of reproductive age (WRA), particularly during pregnancy, is critical for providing the required interventions, maternal and childcare and infrastructures that will mitigate the future risk the epidemics of non-communicable diseases among women. This study investigates the association of maternal obesity and lifestyle factors with glycaemic control, GWG, pregnancy and postpartum outcomes in Ibadan, Nigeria.



Figure 1

Conceptual Framework for the Ibadan Pregnancy Cohort Study GDM – gestational diabetes mellitus GWG – gestational weight gain

MATERIALS AND METHODS

Study design, Setting and eligibility criteria: The Ibadan Pregnancy Cohort Study is a multicentre, prospective cohort study that recruited pregnant women early (gestational age \leq 20weeks) during their first booking antenatal visit at four health facilities. These health facilities include; University College Hospital, Adeoyo Maternity Teaching Hospital, Jericho Specialist Hospital, and Saint Mary Catholic Hospital, Oluyoro in Ibadan, Nigeria. They provide comprehensive obstetric services and are the main referral centres for obstetric emergencies within the Ibadan metropolis. The estimated annual capacity of pregnant women registered for antenatal care in these health facilities are 2500; 4500; 1200; and 600 pregnant women. The number of pregnant women recruited from each health facility was based on their annual delivery rate and were as follows – University College Hospital (442), Adeoyo Maternity Teaching Hospital (757), Saint Mary Catholic Hospital, Oluyoro (99), and Jericho Specialist Hospital (447). The study design is explained by the conceptual framework shown in Figure 1. The primary exposure variable (maternal obesity) and other covariates such as; sociodemographic and lifestyle factors were assessed at baseline. These factors are linked to maternal metabolism (GDM, gestational dyslipidaemia and GWG), pregnancy and postpartum outcomes. The exposure group (n=328) were women with maternal obesity (BMI \ge 30 kg/m2), and the comparison group (n=1328) were women with BMI < 30kg/m2. The primary exposure variable in this study was maternal body mass index at booking (weight/height2). The women were followed up at different time points: recruitment (T0), third trimester (T1), delivery (T2) and 3 -yearspostpartum period (T3). The assessment of biomarkers (fasting blood sugar, one-hour post glucose load, two-hour post glucose load, triglyceride (TG), low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol and total cholesterol) were done between 24 -28 weeks gestation according to guideline (Metzger et al., 2007, Catalano et al., 2012).

The eligibility criteria were women who presented for antenatal care early in pregnancy: gestational age ≤ 20 weeks, aged ≥ 18 years, without pre-existing diabetes mellitus or severe chronic medical disorders like severe hypertension, sickle cell anaemia, or renal disease.

The sample size was estimated using the formula for comparing two proportions

$$n = \frac{1}{(1-f)} * \left(Z \frac{\alpha}{2} + Z \beta \right)^2 * \left[\frac{p_1(1-p_1) + p_2(1-p_2)}{(p_1 - p_2)(p_1 - p_2)} \right]$$

i.e. the proportion of obese (12%) and non-obese (4%) pregnant women with (Ehrenberg *et al.*, 2002) which is the primary outcome, type I error of 5% ($Z_{(\alpha/2)}$ =1.96); type II error of 10% ($Z_{(\beta)}$ =1.28);, and an attrition rate of 40% (to account for loss to follow-up) resulting in 788 participants for the two groups with a design effect of two (788*2) =1576 was the estimated minimum sample size. Overall, 1,745 pregnant women at their first antenatal booking visits were enrolled at baseline in the study.

Ethical Consideration: We obtained the ethical approval for this study from the University of Ibadan/University College

Hospital (UI/UCH) Institutional Review Board (UI/EC/15/0060) and the Oyo State Ministry of Health Ethical Committee (AD/13/479/710). Both verbal and informed consent were obtained from all respondents before recruitment into the study. The study protocol and conduct adhered to the principles laid down in the Declaration of Helsinki: Including Confidentiality of Data: All information collected in this study is confidential, i.e. we will not use names or any identifier in any publication or any reports from this study. Beneficence to participants: Study participants benefitted from close monitoring of their health status, for example, the serial monitoring of their weights, glycaemic control.

Non-maleficence to participants: The risk involved in this study was very minimal, not more than what is expected during routine care. This study did not threaten the participants or their unborn infants. *Voluntariness*: Participation in this study was entirely voluntary, with participants able to opt-out even after they had been enrolled. *Social Justice:* All the pregnant women had the right to participate in the study

Measurement and Assessment: The pregnant women were assessed, and trained research nurses took measurements at baseline, third trimester, delivery, and postpartum. Data was collected using pretested, interviewer-administered questionnaires and desk review of medical and nursing records, discharge summaries etc. We assessed biomarkers between 24 -28 weeks gestation. Table 1 shows the overview of measurements and variables collected in the Ibadan Pregnancy Cohort study protocol.

Variables and possible confounders: The primary exposure variable in this study is body mass index (BMI) as a function of weight (in kg) divided by the square of height (in metre). Maternal obesity was defined as BMI \geq 30 kg/m2 according to the WHO guideline (WHO, 1995). The secondary exposure variables were dietary patterns and physical activity. The significant covariates assessed were sociodemographic status, past obstetric history, household assets, etc. Data were obtained through in-person interviews using standard scales and questionnaires and a desktop review of medical records. Anthropometric measures like weight, height, mid-upper arm circumference were obtained, and serial weight values were used to estimate GWG according to the Institute of Medicine guidelines (2009) (IOM, 2009). GDM was assessed by an oral glucose tolerance test (OGTT), and the lipid profile were conducted between 24 -28 weeks of gestation. Other maternal outcomes were GWG, caesarean-section, postpartum haemorrhage and length of hospital stay. Macrosomia (birthweight \geq 4.0kg), prematurity at \leq 37 weeks, and birth asphyxia (APGAR scores <7) were neonatal outcomes. The overview of measurements and variables collected in the Ibadan Pregnancy Cohort study protocol is shown in Table 1.

Anthropometric Measurement: Camry digital scales (product code 3730270) were used to determine the weight of respondents to the nearest 0.1kg. The height of respondents (in centimetres) was measured using a calibrated metre rule. All anthropometric measurements were obtained with women wearing light clothes and without shoes by trained personnel to ensure uniformity of measurement standards. BMI was

classified according to the WHO cutoff points: underweight (<18.5kg/m2), normal weight (18.5–24.9kg/m2), overweight (25.0–29.9kg/m2), and obese (30kg/m²) (WHO, 1995). Also, gestational weeks at delivery, weight (kg), length (cm) and head circumference (cm) of infants at birth were retrieved from medical records after a desk review by trained personnel.

Blood pressure measurement: Blood pressure readings were recorded at every contact with study participants using the *Omron Automatic Upper Arm Blood Pressure Monitor*. Measurements were taken after participants had been sitting for at least five minutes. Hypertension was described as a systolic blood pressure \geq 140 mmHg and/or diastolic blood pressure \geq 90 mmHg.

Dietary Assessment: The dietary habit of study participants was evaluated using a qualitative food frequency questionnaire (FFQ) with 67 food and drink items to assess respondents' dietary habits three months before their first antenatal visit. All study participants completed the FFQ during their first antenatal visit. Participants were requested to provide information on the frequency of consumption of food and drink items; once daily, more than once daily (i.e. 2 -3 times weekly); once monthly, more than once monthly (i.e. 2 -3 times monthly).

Physical Activity Assessment: Physical activity was assessed using the Pregnancy Physical Activity Questionnaire (PPAQ). The PPAQ was developed and validated by Chasan-Taber to determine the PA levels in pregnant women (Chasan-Taber et al., 2004). It is a 32-item questionnaire that measures the levels of physical activity across five domains - Household and caregiving activities (12 items), occupation (5 items), sports and exercise (12 items), transport (3 items. Each question estimates the frequency, duration of the activity and the level of intensity (sedentary, light, moderate and vigorous). All of which were used to calculate the energy expenditure in the metabolic equivalent task (MET) per minute. The MET is the ratio of a person's working metabolic rate relative to the resting metabolic rate. The total energy expenditure per week and the duration of moderate-intensity activity were estimated using the PPAQ instruction guide (Chasan-Taber et al., 2004).

Assessment of Gestational Diabetes Mellitus and lipid profile: GDM was determined using a three-point 75g Oral Glucose Tolerance Test at 24 - 28 weeks' gestation. The analysis was carried out using the glucose oxidase method (Baker, 1990). The diagnosis of GDM was according to the International Association of Diabetic and Pregnancy Study Group (IADPSG) criteria (Metzger *et al.*, 2007, Catalano *et al.*, 2012). The lipid profile of the pregnant women, which included triglycerides, LDL cholesterol, HDL cholesterol and total cholesterol levels, were also ascertained using enzymatic methods on automated analyser Landwind C 100 plus except for LDL cholesterol that was calculated using the Friedwald formula.

Gestational Weight Gain (GWG): GWG was estimated by the difference between the booking weight and last third trimester

weight recorded. We classified GWG into inadequate, sufficient and excessive gestational weight gain according to the 2009 Institute of Medicine (IOM) guidelines (IOM, 2009).

Psychological Assessment: The psychological assessment included the assessment of antepartum depression, perceived stress and intimate partner violence using the Edinburgh Depression Scale (Cox *et al.*, 1987), Perceived Stress Scale (Cohen *et al.*, 1983) and intimate partner violence (Sherin *et al.*, 1998) instruments, respectively.

Postpartum Assessment: The study's second phase is the postpartum assessment of mothers and their offspring. The postpartum evaluation is scheduled for three years postpartum to enable the assessment of early childhood outcomes. The other postpartum outcomes include postpartum weight retention (\geq 5kg), postpartum dysglycaemia (fasting blood glucose and glycated haemoglobin greater than the specified threshold) and childhood obesity (BMI for age).

Dependent and Independent variables: The primary maternal and neonatal outcomes were Gestational Diabetes Mellitus (GDM) and macrosomia (birthweight \geq 4.0kg), respectively. The secondary maternal outcomes were gestational weight gain rate, caesarean Section, postpartum haemorrhage, length of hospital stay, postpartum dysglycaemia and postpartum weight retention. Gestational age at delivery (prematurity at \leq 37 weeks); APGAR Score at birth (Birth Asphyxia: APGAR score<7) were the secondary neonatal outcomes. Childhood obesity was the secondary childhood outcome. The primary independent variable was maternal obesity (BMI \geq 30 kg/m²), and the secondary exposure variables were dietary Patterns and Physical activity levels. The other lifestyle characteristics included the lifestyle factors examined included consumption of sugar-sweetened beverages, sedentary behaviour, tobacco use, alcohol consumption, sleep pattern. Vital signs of the study participants: systolic blood pressure (SBP), diastolic blood pressure (DBP) and pulse rate were also obtained as repeated measures.

Statistical analysis: We used descriptive statistics for summarising data using mean \pm standard deviations, median and interquartile range for continuous variables and proportions for categorical variables. Bivariate analyses was used to examine the association between the independent and dependent variables. T-test and ANOVA for significant mean differences of continuous variables that fulfil the normality assumptions and Wilcoxon rank-sum or Kruskal-Wallis as non-parametric tests. Chi-square and Fishers for the test of proportions. Dietary and physical activity patterns was derived using factor analyses. Regression analyses (including linear, logistic, Poisson, multinomial or negative binomial) will be utilised to estimate effect sizes and the confidence intervals depending on the type of outcome. For example, logistic and Poisson regression will be used to assess the relationship between maternal obesity and gestational diabetes mellitus, then pregnancy outcomes, respectively. We set statistical significance at p<0.05

Table 1:

Overview of measurements and variables collected in the protocol of the Ibadan Pregnancy Cohort study

Method	Variables	Time-	Time-point*			
Core protocol		Т0	T1	T2	Т3	
Demographic background	Age	\checkmark			\checkmark	
	Highest Education					
	Religion					
	Marital Status, Ethnic group etc.					
	Spouse/Partner profile					
Socio-Economic Status (SES)	Occupation, Income					
	Family Income, Household assets & characteristics etc					
Lifestyle characteristics	Smoking history	\checkmark			\checkmark	
	Alcohol and Beverage consumption					
	History of contraceptive use				\checkmark	
Sleep	Sleeping hours, Difficulty in sleeping etc.	\checkmark			\checkmark	
Physical Activity	Pregnancy Physical Activityusing PPAQ	\checkmark			\checkmark	
Food and dietary intake	Food frequency using FFQ					
Obstetric, Birth and Medical histories	Gestational age		\sqrt{a}	\sqrt{a}		
	Last menstrual period, Parity, Gravida etc		\sqrt{a}	\sqrt{a}		
	Birth histories, experience(s) & complication(s)	\checkmark	\sqrt{a}	\sqrt{a}		
	Family history of diseases		\sqrt{a}	\sqrt{a}		
	Medical condition(s) etc		\sqrt{a}	\sqrt{a}		
Body composition	Weight, Height, etc					
	SBP, DBP. Pulse rate etc				\checkmark	
Pregnancy complications and	Hospital admission during pregnancy					
management	Antenatal visits					
	Self-medication/herbal concoction use					
Psychological factors	Depression					
	Perceived Social Support		1			
	Intimate partner violence					
Fetal characteristics	Ultrasound report	\checkmark		\sqrt{a}		
Biological samples	Glucose, Insulin, Lipid profile etc				\checkmark	
Delivery experience	Total ante-natal checks, Type of delivery, etc			\sqrt{a}		
	Gestational age at admission for delivery					
	Symptoms of labour presentation					
	Fetal presentations at labour etc					
	Complications; maternal or fetal etc			\checkmark		
Peri-natal outcomes	Pregnancy outcome, GA at delivery etc					
	APGAR Score, Sex of infant, Birth weight & length					
Family Support	Having special person around, family support, etc					
Pregnancy-related/labour cost	Medical cost and expenditure during labour					
Postpartum issues	Postpartum weight retention, postpartum dysglycaemia, childhood obesity					

* Time point at recruitment, GA-gestational age, SBP-systolic blood pressure, DBP-diastolic blood pressure, FFQ-food frequency questionnaire, PPAQ- Pregnancy Physical Activity Questionnaire

a-variable(s) were assessed more than once for the purpose validation

* Timepoints of follow-up: T0 - Baseline; T1 – Third trimester; T2 – Delivery; T3 – Post-partum period

RESULTS

The overview of measurements and variables collected in the Ibadan Pregnancy Cohort study protocol is shown in Table 1. We captured the background characteristics, including sociodemographic, socio-economic status and lifestyle characteristics, namely dietary pattern, physical activity, sleep pattern etc., past obstetric history during enrolment (T0). Biomarkers and pregnancy complications were assessed during the third trimester (T1), while delivery outcomes were abstracted from medical records (T2). We will determine the postpartum outcomes and lifestyle characteristics at three years following the index pregnancy (T3). Repeated measures

in the study included maternal weight and vital signs, including blood pressure.

DISCUSSION

Maternal obesity has emerged as a serious but neglected public health issue in LMIC. This is because of the associated adverse metabolic, pregnancy, postpartum outcomes and an increased future risk of type 2 diabetes, cardiovascular diseases and chronic renal failure among women of reproductive health (Godfrey et al., 2017, Hanson et al., 2017). Maternal obesity also has a transgenerational effect on the offspring by increasing the risk of childhood obesity and cardiometabolic risk (McGuire et al., 2010, Gillman, 2016). Sustainable Development Goal 3 aims to ensure healthy lives, promote well-being for all ages, and reduce the global MMR to 70 per 100,000 (UNDP, 2015). Currently, MMR in Nigeria is 580 maternal deaths per 100,000 live births (WHO, 2019), and the health system/infrastructure has been structured mainly for managing infections and undernutrition and not maternal obesity and associated complications. This new challenge may reverse the gains of maternal and child mortality reduction efforts in Nigeria (Abegunde et al., 2015). Fortunately, pregnancy and postpartum period allow pregnant women to interact with the health sector. Besides, women are more willing to adopt behavioural and lifestyle changes that can improve their health and that of the children. Hence, women can be targeted for health interventions at this period..

Unfortunately, maternal obesity and associated factors/consequences have received scant attention in research and maternal health care in LMIC, particularly Nigeria. For example, even though maternal weights are measured during antenatal care, this exercise hardly informs clinical decisions such as identifying excessive weight gain in pregnancy. Excessive weight gain is a significant cause of maternal obesity, postpartum weight retention and their consequences among WRA in Nigeria (Kandala and Stranges, 2014, Onwuka et al., 2017). Hence, investigating the association of maternal obesity with the lifestyle factors (importantly dietary pattern and physical activity), on glycaemic control, GWG, pregnancy and postpartum outcomes is necessary for designing well-articulated policy formulation, engagement and cost-effective interventions to mitigate the risk, halt and reverse the impact of maternal obesity on maternal and child health not only in Nigeria but also in sub-Sahara Africa. For example, this study will provide empirical evidence for providing lifestyle interventions (Bick et al., 2020, Louise et al., 2021) These interventions include promoting a healthy lifestyle during pregnancy, preventing excessive gestational weight gain, postpartum weight-loss strategies, reversing pregnancy-associated glucose metabolism disorders to mitigate the risk of future chronic diseases among Nigerian women. We will disseminate the outcome of this research disseminated through scientific publications, conferences, policy and community engagement. The main strength of our study is the prospective cohort design utilised, which enabled the investigation of multiple risk factors and multiple outcomes. The multicenter approach also improved the external validity of the study. The assessment of biomarkers on pregnancy outcomes was also a critical component of the

study. However, it has limitations, including the loss of follow-up, which is typical of prospective studies, misclassification bias from self-reported measures, etc.

In conclusion, the Ibadan Pregnancy Cohort Study is the first multicentre prospective cohort study to investigate maternal obesity and lifestyle characteristics, including dietary habits and physical activity on glycaemic control, GWG, pregnancy and postpartum outcomes in Nigeria. This study provides the needed empirical evidence for mitigating the short- and long-term effects of maternal obesity through antenatal and postpartum lifestyle interventions. Hence, future studies should focus on implementing and testing different strategies through interventional studies to tacking the scourge of maternal obesity in Nigeria.

Authors' contributions

IAA conceived the research idea, designed and conducted the study under the supervision of EAB and AOO. IAA analyzed the data and wrote the initial and final versions of the manuscript. EAB and AOO reviewed the manuscript. All authors read and approved the final manuscript.

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