Improving malaria preventive practices and pregnancy outcomes through a health educational intervention: a randomized controlled trial

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Abstract
Background: The prevalence of malaria in pregnancy and its complications, remain very high in Nigeria. This study aimed to determine the effects of a malaria health educational intervention based on the information-motivation-behavioural skills (IMB) model on malaria preventive practices and pregnancy outcomes.

Methods: The study was a randomized controlled parallel-group study, where 372 randomly selected antenatal care attendees were randomly assigned to one of either two groups after collecting baseline data. The intervention group then received a four-hour health education intervention developed based on the IMB model, while the control group received a similarly designed health education on breastfeeding, and were then followed-up to the end of their pregnancies. The intention-to-treat analysis using the generalized linear mixed models was used to analyse the data obtained.

Results: The reported frequency of ITN use and dose of IPTp taken, were higher in the intervention group by 0.32 levels (p =0.024) and 0.37 doses (p <0.001) respectively, implying that for 32% and 37% of the participants, an individual in the intervention group slept more frequently under an ITN by one day, and had also took one dose of IPTp more than an individual in the control group. The intervention group also achieved a haematocrit level of 0.80% higher than the control group. The intervention however, had no significant effect on the incidence of malaria diagnosis or babies’ birth weights.

Conclusion: The intervention was effective in improving ITN use, IPTp uptake, and haematocrit levels. It is therefore recommended for the module to be adopted and incorporated into the routine antenatal care programmes in the state.

Introduction
Malaria infection remains endemic in many countries including Nigeria [1], which contributed the largest percent of cases (27%) to its global incidence in the year 2016 [2]. Complications like anaemia [3, 4], abortion, [5, 6], stillbirth [7, 8], low-birth weight [9, 10], and pre-term delivery [7] could arise from malaria infection during pregnancy. The World Health Organization recommends that all pregnant women living in malaria-endemic regions of sub-Saharan Africa always sleep under an
insecticide-treated net (ITN), and take monthly doses of intermittent preventive treatment in pregnancy (IPTp) with Sulphadoxine-pyrimethamine (SP), starting from the second trimester of pregnancy [11]. Systematic reviews of trials have also shown that sleeping under an ITN [12, 13] and IPTp [14, 15] greatly decrease the risk of malaria infection and its complications during pregnancy. In Maiduguri, Nigeria, the prevalence of malaria parasitaemia at the time of booking, among randomly selected pregnant women was 60.3% [16]. A prevalence of 48.1% had also been reported among antenatal care attendees of a secondary health centre [17], while a prevalence of 33.9% [18] and 44.5% [19] had been reported in a tertiary centre in the same city. Even the adverse events which could occur as complications of malaria in pregnancy, are highly prevalent in Maiduguri. A four-year retrospective study at a tertiary centre in Maiduguri revealed a neonatal mortality rate of 349 per 1,000 live births; and 62.1% of these deaths were among pre-term infants [20]. Out of 718 women admitted to the gynaecology ward in the three main public hospitals in Maiduguri, 17.5% had a history of spontaneous abortion, 23.1% of which were attributed to malaria, typhoid, or other like febrile illnesses [6]. Also in a tertiary hospital in Maiduguri, out of 7,996 deliveries, there were 23 stillbirths per 1,000 live births [21]. A prospective study among pregnant women in the same centre revealed a prevalence of 16.9% for low birth weight [22].

Despite this high prevalence of malaria infection in Maiduguri, the level of compliance with these recommended preventive measures has been very poor, as only 2.3% of the pregnant women attending a tertiary health centre were sleeping under an ITN [16]. Overall in Borno state, a survey among pregnant women between the ages of 15–49 years showed that only 13.8% of them were using ITNs, while only 13.9% had received any single dose of IPTp [23]. Another peculiarity with Maiduguri is the presence of internally-displaced persons (IDPs), from various local government areas of Borno and some neighbouring states, following the Boko Haram insurgency [24]. According to the International Organization for Migration (IOM), Borno state has the highest number of IDPs of all the 36 states in Nigeria, numbering 672,714, with Maiduguri hosting 432,785 [25]. Being internally-displaced has been associated with a number of health problems [26].

Notwithstanding the high prevalence of malaria among pregnant women in the region, the serious
associated complications, and the low compliance with prescribed preventive measures, no interventions have been specifically developed for antenatal care attendees to boost their level of compliance with these preventive practices, and by extension, reduce the incidence of malaria infection and its associated adverse consequences. A health education intervention on malaria based on the Protection-Motivation Theory (PMT) was effective in improving both self-efficacy and preventive practices [27] which points the important role health theories are likely to play in achieving a health behaviour change. However, the PMT fails to identify other environmental and cognitive factors that can affect attitude change [28]. The Information-Motivation-Behavioural skills (IMB) theory on the other hand has three components which are information about the health behaviours, motivation to carry out such behaviours, and the requisite skills for performing such behaviours [29]. This model has also been used not only to predict health behaviour, but also the subsequent health outcomes as a result of changing those health behaviours [30]. This study aimed to determine the effects of a health educational intervention based on the information-motivation-behavioural skills theory on malaria knowledge, motivation and behavioural skills, as well as malaria preventive practices and pregnancy outcomes. As this study had both primary and secondary outcomes, the results of the primary outcomes which are psychological constructs (malaria knowledge, motivation and behavioural skills), have been presented separately elsewhere [31], while this paper focuses on the secondary outcomes which are behavioural and clinical factors (ITN use, IPTp uptake, haematocrit, malaria infection, and pregnancy outcomes).

Materials And Methods

Study area

The study area was Maiduguri, the Borno state capital which is located in North-eastern Nigeria. Borno state lies between latitudes 10° 30' and 13° 50' north and longitudes 11.00° and 13° 45' east, with a total land area of 69,435 km² [32]. The climate varies according to the time of the year, with temperatures ranging from 25°C to 44°C, and an average annual rainfall of 613 mm [32]. Its population is reported to be 540,016 consisting of 282,409 males and 257,607 females [33]. The study location which was the State Specialist Hospital, is one of the three secondary-level hospitals in
Maiduguri, Bono State. It was chosen because it happens to be the biggest of the three state hospitals in terms of size, man-power and patient load. Its location is also at the centre of the city, making it the most geographically accessible, to the Maiduguri populace. The ante-natal care clinic is run as a unit under the Department of Obstetrics and Gynaecology, and is run from Mondays to Fridays. Mondays are reserved for booking, while follow-up visits are conducted on the other days. Each booking clinic session has an average load of approximately a hundred clients. Booking at the hospital’s clinic is open to all pregnant women, irrespective of their gestational ages, and with no requirement for referral letters from other centres. Routine antenatal health education is given by the mid-wives at the waiting hall, before antenatal care consultations start. The talks given are not structured, and cut across issues of hygiene, proper nutrition, breastfeeding, malaria prevention and any health issue deemed relevant by the staff.

Study Design And Study Population

The study was a double-blind parallel-group randomized controlled trial guided by the CONSORT Statement [34]. Participants were randomly selected from the ante-natal care attendees, and then randomly assigned to either the intervention or control group (with equal number of participants in each group). The intervention group received the IMB-based health educational intervention on malaria, while the control group received health education on breast feeding. The study population was pregnant women attending the State Specialist Hospital, Maiduguri for their ante-natal care. Those who do not understand Hausa language were excluded because the intervention was prepared and delivered in Hausa language. Also excluded were participants who had history of medical conditions which could interfere with the study outcomes like: hypertension, pre-eclampsia or eclampsia [35–37], diabetes [38, 39] and history of per vaginal bleeding in index pregnancy [40]. The minimum sample size required to test the study hypotheses was calculated using the two proportions formula [41]. In a previous study which had included ITN use and IPTp [42], substituting the results of ITN use (P = 0.295; P₁ = 0.38; P₂ = 0.21) gave a higher sample size. Subsequent adjustments were made for an estimated 30% drop out, and an estimated eligibility of 70%, to give a final sample size of 352 (176 participants in each group).
Randomization

Random assignment of the participants to either the intervention or control group, was done on the same day the participants were selected into the study. It was however performed after baseline data had been collected.

Sequence Generation

The permuted block randomization technique was used. Permuted blocks of four (each containing two interventions and two controls), containing all the six possible combinations (AABB, BBAA, ABBA, BAAB, ABAB, BABA) were generated using the random function in Microsoft Excel 2013.

Allocation Concealment Mechanism

The sequences generated were then placed inside opaque envelopes and sealed, by the medical records’ staff who generated them. The envelopes were also serially numbered from the outside, to guide those doing the allocation.

Implementation

The sequence generation was performed by a trained staff of the hospital’s Medical Records Department, who was not part of any of the other research processes. Two other staff of the antenatal clinic worked independently to assign groups to the participants. The first staff serially handed over the envelopes to the participants without opening, then directed them to the second staff. The second staff then opened the envelopes, informed them of the day to come for their health education session (based on the group to which they belonged), and then documented their respective groups on a sheet provided. Each participant was then given a hand card, which carried their bio-data and serial numbers. The hand card also contained a short note indicating that they had been enrolled into a follow-up study, and requesting of the attending physician or nurse to kindly complete the post-natal findings as indicated on the card.

Blinding

The study was double-blinded, as participants and assessors (enumerators) were blinded to the assigned interventions. The list of assignments was then kept confidential by the staff who documented the participants’ allocations. This staff was only aware of the group coding (A and B), but
unaware of the interventions assigned to them. To ensure blinding of the participants, the groups they belonged to, were not indicated on their cards. The subsequent clinic appointment dates for the two groups were set on different days, to minimize contamination. The enumerators were blinded, as they were not involved in any of the processes of group allocation, or delivery of the intervention.

Development Of The Health Educational Intervention Modules

For the malaria health educational intervention, the information sources for developing the modules were: the National Guidelines and Strategies for Malaria Prevention and Control During Pregnancy, a publication of the Nigerian Federal Ministry of Health [43]; WHO published materials [11, 44]; publication of the Global Health Learning Centre on Malaria in Pregnancy [45]; and other publications from studies carried out in Nigeria. It was developed based on the Information-Motivation-Behavioural Skills theory [29], using local scenarios for demonstration purposes. The breastfeeding modules were developed from the following sources: National Policy on Infant and Young Child Feeding in Nigeria [46]; Lactation Management Self-Study Modules, Level I [47] and other studies conducted in Nigeria on breastfeeding practices. The items extracted from these sources were compiled to follow a similar pattern with that for the malaria health education intervention. This topic was chosen because of its relevance to their pregnancy state (that is, being prospective mothers).

Structure Of The Malaria Health Educational Intervention Modules

The intervention consisted of four modules, covering each of the constructs of the IMB model as presented in Table 1. The first and second modules covered the information construct, the third module covered the motivation construct, while the fourth module covered the behavioural skills construct.
Table 1
Tabular illustration of the malaria intervention modules by construct and contents

| Theory Construct | Module & Strategy | Contents | Estimated time |
|------------------|-------------------|----------|----------------|
| Information      | Modules 1 & Module 2 (Lectures) | Transmission; Clinical features; Complications; Prevention measures | 30 minutes & 30 minutes |
| Motivation       | Module 3 (Interactive discussion; Brainstorming) | Participants’ experiences and those of other pregnant women | 1 hour 30 minutes |
| Behavioural skills | Module 4 (Lectures; Videos; Demonstrations) | Evaluation of self-efficacy for taking IPTp-SP and using ITN; Goal setting | 1 hour 30 minutes |

The first module was titled ‘Understanding Malaria in Pregnancy’. This module gave a general discussion on malaria in pregnancy, at the end of which the participants were expected to be able to identify what causes malaria; its mode of transmission; its signs and symptoms; its complications during pregnancy; and how it can be prevented. This section was delivered basically through lectures.

The second module was titled, ‘The Main Preventive Measures for Malaria in Pregnancy’ which introduced the two most important preventive measures for malaria during pregnancy (TN use and IPTp uptake). This module discussed the importance and efficacy of these preventive measures, as well as success stories of these measures as reported in some studies. Participants were expected to be able to highlight the protective importance of IPTp and ITN at the end of this section. This section was also delivered through lectures.

The third module was titled, ‘Motivation for Malaria Prevention during Pregnancy’, and it dwelt on motivating the participants to adopt these protective measures. This module was designed to guide an interactive session, for misconceptions and other possible deterrent factors to be addressed interactively. The facilitator together with the participants were to brainstorm and proffer possible ways of overcoming those deterrent factors. At the end of this session, participants were expected to be apparently convinced of the efficacy and safety of these preventive measures, and also motivated to carry them out. The fourth module titled, ‘Insecticide Treated Net and Fansidar’, focused on empowering the participants. They were to be practically shown how to hang, and care for their insecticidal nets, and how to look out for defects in their nets, and how to repair them. They were also taught about the timings, indications and contra-indications for IPTp, and also educated on how to
take their drugs. Their level of self-efficacy was to be assessed at a group level, and collectively, goals were set to achieve better adherence to these malaria preventive measures. There were evaluation questions at the end of Modules 1, 2 and 4.

Structure Of The Breastfeeding Health Educational Intervention Modules

The intervention consisted of three modules, covering each of the constructs of the IMB model. As presented in Table 2, the first module covered the information construct, the second module covered the motivation construct, while the fourth module covered the behavioural skills construct. The first module titled, ‘An Overview of Breastfeeding’ had two sections: the first section was on the benefits of breastfeeding and the consequences of not breastfeeding; while the second section discussed the practices to avoid during breastfeeding, alternatives to breastfeeding, and challenges associated with breastfeeding such as sore nipples, low milk supply and breast engorgement. The second module titled, ‘Motivation on Breastfeeding’ contained a list of misconceptions and other deterrent factors for exclusive breastfeeding as identified in previous studies. These were to be discussed and brainstormed by the participants under the facilitator’s guidance to come up with solutions. The third module titled, ‘Practical Session’ was for breastfeeding procedures to be demonstrated practically using models as well as video demonstrations to be shown to the participants.

Table 2

| Theory Construct | Module & Strategy | Contents | Estimated time |
|------------------|-------------------|----------|----------------|
| Information      | Module 1 (Lectures) | Benefits of breastfeeding, Consequences of not breastfeeding, Problems associated with breastfeeding. | 30 minutes |
|                   |                   |          | 1 hour |
| Motivation        | Module 2 (Interactive discussion; Brainstorming) | Participants’ experiences and those of other pregnant women | 1 hour 30 minutes |
| Behavioural skills | Module 3 (Lectures; Videos; Demonstrations) | Practical demonstrations of breastfeeding techniques; expression of breast milk | 1 hour |

Quality Control Of The Health Educational Interventions

This entailed appraising the modules for accuracy, relevance and comprehensibility, as well as giving the facilitator adequate training on the modules.

Quality Control Of The Module Contents
The modules for the intervention group as well as the control group were appraised for their contents and relevance by expert teams. For the malaria health educational intervention modules, the team comprised of three Public Health specialists, an Obstetrics and Gynaecology specialist, a Health Educator, and a Midwife; while the appraisal team for the modules on breastfeeding comprised of three Public Health specialists, a Health Educator, and a Paediatric nurse. Both interventions were pre-tested with a sample of twenty five pregnant women from the same hospital, who were not part of the study. Appropriate feedback was then obtained, from both the experts as well as the participants, and appropriate modifications and corrections were effected.

Training Of The Module Facilitator

One facilitator who was a midwife was chosen to deliver the modules at all the health education sessions for both groups. For each of the two interventions, the facilitator received two sessions of one-on-one training by the researcher. The first session lasted about four hours long, during which the contents of the modules, and how to deliver them within their limits were treated. A revision session was then held again in a similar way after the module had been revised (after the pre-testing).

Delivery Of The Malaria IMB-based Health Educational Intervention

The interventions were given a week after baseline data had been collected. As suggested by McMillan, delivery of educational interventions should be in modes that are consistent with what is used in practice [48], and as such, they were given at a group level, and in a single-session, with each session having around fifty participants. The module was delivered by the facilitator (a midwife nurse), so as to eliminate experimenter effects. The facilitator was blinded to the objectives of the study, and delivery of the module was also closely monitored and supervised by the researcher, while giving necessary feed-back to the facilitator to ensure that the module was strictly followed without straying. The facilitator went through all the four modules, while actively engaging the participants. The durations were approximately 30 minutes, 30 minutes, 1 hour 30 minutes and 1 hour 30 minutes, for modules 1, 2, 3 and 4 respectively, with breaks of about 10 to 15 minutes between modules. Each participant was given the chance to demonstrate what she had learnt, and corrective feed-back was given.
Delivery Of The Breastfeeding Health Educational Intervention

The health education modules on breastfeeding were delivered by the same midwife who gave the malaria health education. The total duration of the session was also around four hours, and the delivery was of similar methodology to that of the malaria health education modules, comprising of lectures with power-point presentations, videos, discussions, and practical sessions. A paediatric nurse helped out with the demonstrations using models. The delivery was also strictly monitored to ensure strict adherence to the module and its contents, without straying.

Follow-up Of Participants

After collecting baseline data, randomization, and delivery of the intervention, participants were then followed up. Follow-up data was collected using the same questionnaire, at 2-months post-intervention and at 4-months post intervention. Participants were also requested to always carry their hand cards with them each time they visited the hospital, especially when they were going for delivery, or in the case of a home delivery, to present to the hospital immediately. Data on babies’ birth weights and pregnancy outcomes were filled on the hand card by the attending physician or nurse, which participants submitted back after their delivery. For each visit, compensation for transport fare was given to each participant.

Variables

The independent variable in this study was group, which was either the intervention or control group. The dependent variables comprised of primary outcomes (ITN use and IPTp uptake) and secondary outcomes (malaria diagnosis, haematocrit, pregnancy outcome, and babies’ birth weights). Other variables which were considered potential confounding factors in this study, included ethnicity, family type, type of residence, educational status, occupational status, income level, age at first marriage, gravidity; parity, period of amenorrhoea, history of previous preterm delivery, and history of previous miscarriage.

A monogamous family was defined as one with one husband and one wife, while a polygamous family was defined as one in which the husband had more than one wife [49]. An internally-displaced person (IDP) was defined as a Nigerian who had been displaced from her town of residence, but not outside
the country, as a result of armed conflict situation [50]. The Nigerian minimum wage of N18,000 was used to categorize monthly income. A live birth was defined as one in which there was any sign of life after expulsion from the mother, irrespective of the gestational age [51], while a stillbirth was defined as a baby born after 28 weeks of gestation with no signs of life [52]. A baby was defined as low birth weight, if its birth weight was below 2.5 kg [53].

Instruments And Data Collection Methods

The instruments used for data collection in this study were the questionnaire and study hand card. Due to low literacy rates, the questionnaires were administered as face-to-face interviews in Hausa language, by trained enumerators. The questionnaire had four sections: socio-demographic characteristics; obstetric and gynaecological history; preventive measures; malaria infection and haematocrit. The section on preventive measure asked about how frequently they slept under an ITN, and whether or not they had taken IPTp, and the number of doses. Frequency of ITN use was categorized as: Never, Seldom (1-2 times a week), Sometimes (3-4 times a week), Often (5-6 times a week) and Almost always. These categories were scored: 1, 2, 3, 4 and 5 respectively. History of malaria was based on self-reporting, and a client was said to have had malaria if she had been told so in a health centre, after a blood test. Their haematocrit measurements were obtained from their ante-natal cards as it is routinely done in the ante-natal clinic.

The study hand cards were designed by the researchers to collect information about post-pregnancy events. They were given the cards immediately after recruitment, and were to be submitted to the researcher at the end of the pregnancy. It contained the participants’ serial numbers, basic bio-data, and a short appeal to the attending physician or nurse, informing them that the patient had been enrolled into a follow-up study, and his/her help was required to kindly complete the blanks provided on the card. The items it contained were: outcome of pregnancy (live birth, stillbirth or miscarriage), place of delivery (hospital/health centre or home) and baby’s birth weight. For those who gave birth at home, only information on pregnancy outcome and place of delivery were collected when they came to submit the study cards.

Statistical Analyses
Data collected from the questionnaires and study hand cards were entered into the IBM Statistical Package for Social Sciences (SPSS) version 22, followed by data cleaning. The data set for this study are available as supplementary material. Histogram and absolute values of skewness and kurtosis of not more than 2 and 7 respectively, were used to check for normality of the haematocrit and birth weights [54]. The outcome showed that there was no substantial non-normality in these continuous variables, and as such the data could be treated as normally distributed. Mean and standard deviation were used to summarize continuous variables, while the categorical variables were summarized as frequency and percentage. Pearson’s Chi-squared test was used to compare the baseline and follow-up categorical variables of the two groups. Fisher’s Exact test was performed for variables where any cell had less than five expected observations. Independent t-test was performed on the haematocrit and birth weights to determine the between-group differences in these variables.

The intention-to-treat (ITT) analysis was performed after replacing missing values [55], for which the multiple imputations method was used. This method was chosen since some correlations were expected between the missing observations, such that non-missing values on one outcome can inform the imputation of missing values on another outcome [56]. An exploration of the missing data showed that 11.09% and 13.96% of the data of the intervention and control groups were missing respectively. The Little’s Missing Completely at Random (MCAR) test was not significant ($\chi^2 = 140$, df = 137, $p = 0.400$) for both groups, making the multiple imputations method suitable [57]. The baseline variables were used only for prediction, while the outcome variables were imputed and used for prediction as well. The output of the multiple imputations analysis generated five different data sets which is the default in SPSS, each with missing values replaced. These were then pooled into a single data set for subsequent analyses.

The Generalized Linear Mixed Models (GLMM) analysis was performed to determine the overall effectiveness of the intervention [58]. Twelve potential confounding factors (ethnicity; family type; type of residence, educational status, occupational status, income level; age at first marriage; gravidity; parity level; period of amenorrhoea; history of previous preterm delivery, and history of previous miscarriage) plus the baseline data for the outcome variable in question were included in the
GLMM analysis. The combination of these variables gave the best model, with the lowest Akaike Corrected Information Criterion (ACIC) and Bayesian Information Criterion (BIC). The small intervention groups were entered as the third cluster level, after the identifier (serial number) and intervention group. For sensitivity analysis, the GLMM analysis was repeated without the replacements (per-protocol), to determine the effect of drop out and non-response on the findings of the study. For all analyses, Confidence Interval (CI) of 95% was used, and level of significance was set at 0.05.

Results
The stages through which participants were finally selected into the study are presented in Fig. 1. Study participants were recruited from eight booking clinic sessions from 30 January, 2017 to 13 March, 2017 and the last data on pregnancy outcomes was obtained on 21 September, 2017, after which no more participant had returned. Three hundred and seventy two pregnant women were finally selected to participate in the study, with 186 in the intervention group and 186 in the control group. Most of the participants in the intervention (81.2%) and control groups (85.5%), had attended their respective health education sessions. At 4-months post-intervention, 25.3% and 31.2% from the intervention and control groups respectively, had dropped out of the study.

Participants’ baseline characteristics
Table 3 compares the baseline socio-demographic characteristics of the intervention and control groups. Apart from place of residence, there was no significant difference between the groups in all the factors studied. The control group had a higher proportion of IDPs compared to the intervention group.
### Table 3
Baseline comparison of socio-demographic characteristics between intervention and control groups

| Socio-demographic factor | Groups          |         |         |
|--------------------------|-----------------|---------|---------|
|                          | Intervention    | Control |         |
|                          | FrEq. (%)       | FrEq. (%)|
|                          | (n = 186)       | (n = 186)|
| Age (years)              |                 |         |         |
| Mean (SD)                | 26.1 (5.8)      | 26.9 (5.9) |
| (Range)                  | (15–40)         | (17–45)  |
| Ethnicity                |                 |         |         |
| Kanuri                   | 73 (37.7)       | 63 (33.9) |
| Hausa                    | 30 (16.1)       | 28 (15.1) |
| Babur                    | 13 (7.0)        | 18 (9.7)  |
| Shuwa                    | 6 (3.2)         | 12 (6.4)  |
| Marghi                   | 14 (7.5)        | 12 (6.4)  |
| Fulani                   | 21 (11.3)       | 17 (9.1)  |
| Others                   | 32 (17.2)       | 36 (19.4) |
| Family type              |                 |         |         |
| Monogamous               | 143 (76.9)      | 144 (77.4) |
| Polygamous               | 41 (22.0)       | 42 (22.6) |
| Widowed                  | 2 (1.1)         | 0 (0.0)   |
| Educational status       |                 |         |         |
| None                     | 82 (44.1)       | 71 (38.2) |
| Primary                  | 32 (17.2)       | 32 (17.2) |
| Secondary                | 54 (29.0)       | 54 (29.0) |
| Tertiary                 | 18 (9.7)        | 29 (15.6) |
| Employment status        |                 |         |         |
| None                     | 104 (55.9)      | 101 (54.3) |
| Self-employed            | 56 (30.1)       | 65 (34.9) |
| Government               | 9 (4.9)         | 9 (4.9)   |
| Private                  | 14 (7.5)        | 10 (5.4)  |
| Student                  | 3 (1.6)         | 1 (0.5)   |
| Income                   |                 |         |         |
| None                     | 106 (57.0)      | 102 (54.8) |
| < 18,000                 | 65 (34.9)       | 72 (38.7) |
| ≥ 18,000                 | 15 (8.1)        | 12 (6.5)  |
| Type of Residence        |                 |         |         |
| Permanent resident       | 127 (68.3)      | 147 (79.0) |
| IDP                      | 59 (31.7)       | 39 (21.0) |

The age at first marriage of the respondents ranged from 12 to 34 years, with the mean (SD) age at first marriage being 18.0 (3.3) years. Majority of them (55.1%) had their first marriages during the ages of 16 to 19 years, and only 12.9% were primigravid women. Nulliparous women constituted 14.2% of the participants, while 21.2%, 40.9% and 23.7% were respectively primiparous, multiparous, and grandmultiparous. About a fifth of them (19.6%) had experienced having a pre-term delivery, while a little over a quarter (27.4%) had experienced at least a miscarriage. Only 192 (51.6%) respondents could state the dates of their last menstrual period (LMP), of which that for only 39 (10.3%) participants, were congruent with their period of amenorrhoea stated in months. A baseline comparison between the two groups, by their obstetric and gynaecological characteristics, is presented in Table 4. There was no significant difference between the groups in terms of their age.
groups of first marriage, gravidity, parity, gestational age at booking, history of previous pre-term delivery or previous miscarriage.

Table 4
Baseline comparison of obstetric and gynaecological characteristics between intervention and control groups

| Variables                  | Groups                | FrEq. (%) | FrEq. (%) |
|----------------------------|-----------------------|-----------|-----------|
|                            | Intervention (n = 186) | Control (n = 186) |
| Age at first marriage      |                       |           |           |
| ≤ 15                       | 41 (22.0)             | 35 (18.8) |
| 16–19                      | 105 (56.5)            | 100 (53.8)|
| 20–24                      | 32 (17.2)             | 40 (21.5) |
| ≥ 25                       | 8 (4.3)               | 11 (5.9)  |
| Gravidity                  |                       |           |           |
| Primigravida               | 24 (12.9)             | 24 (12.9) |
| Multigravida               | 96 (51.6)             | 96 (51.6)|
| Grandmultigravida          | 66 (35.5)             | 66 (35.5)|
| Parity                     |                       |           |           |
| Nullipara                  | 28 (15.0)             | 25 (13.4) |
| Primipara                  | 39 (21.0)             | 40 (21.5) |
| Multipara                  | 77 (41.4)             | 75 (40.3) |
| Grandmultipara             | 42 (2.6)              | 46 (24.7) |
| Gestational age booking    |                       |           |           |
| 4 months                   | 49 (26.3)             | 65 (34.9) |
| 5 months                   | 137 (73.7)            | 121 (65.1)|
| History of pre-term delivery |                     |           |           |
| Yes                        | 37 (19.9)             | 36 (19.4) |
| No                         | 149 (80.1)            | 150 (80.6)|
| History of miscarriage     |                       |           |           |
| Yes                        | 49 (26.3)             | 53 (28.5) |
| No                         | 137 (73.7)            | 133 (71.3)|

Participants' Reported Baseline Preventive Practices, Malaria Infection, And Haematocrit

Most of the respondents (89.24%) reported ever sleeping under any type of mosquito net, but only 43.0% reported ever sleeping under an insecticide-treated net during their index pregnancy. Less than a half (42.7%) had received their first dose of IPTp. Three hundred and twenty three (86.82%) of the respondents had their haematocrit results at baseline, with values ranging from 20.0–43.0%, and a mean (SD) haematocrit of 32.8 (3.9) percent. Table 5 shows that both groups did not differ significantly in their reported use of ITN, IPTp uptake, malaria diagnosis, and haematocrit.
Table 5
Baseline comparison of reported malaria preventive practices, history of malaria, and haematocrit between groups

| Variable                        | Group            |   | x²  | df | p   |
|---------------------------------|------------------|---|-----|----|-----|
|                                 | Intervention FrEq. (%) n = 186 |   |     |    |     |
|                                 | Control FrEq. (%) n = 186 |   |     |    |     |
| Reported ITN use                |                  |   | 7.434 | 4  | 0.115 |
| Never                           | 113 (60.8)       | 99 (53.2) |     |    |     |
| Seldom                          | 10 (5.4)         | 18 (9.7)  |     |    |     |
| Sometimes                       | 20 (10.7)        | 16 (8.6)  |     |    |     |
| Often                           | 26 (14.0)        | 23 (12.4) |     |    |     |
| Almost always                   | 17 (9.1)         | 30 (16.1) |     |    |     |
| Reported IPTp uptake in index pregnancy |                  |   | 0.275 | 1  | 0.600 |
| Yes                             | 77 (41.4)        | 82 (44.1) |     |    |     |
| No                              | 109 (58.6)       | 104 (55.9) |    |    |     |
| Reported malaria diagnosis      |                  |   | 0.650 | 1  | 0.420 |
| Yes                             | 49 (26.3)        | 56 (30.1) |     |    |     |
| No                              | 137 (73.7)       | 130 (69.9) |    |    |     |
| Haematocrit                     |                  |   | 1.573 | 321| 0.117 |<sup>a</sup> |
| Mean (SD)                       | 33.09 (4.00)     | 32.42 (3.71) |     |    |     |

Note: (<sup>a</sup>) - p for t-test

Follow-up comparison of reported malaria preventive practices and maternal clinical conditions between the groups

As shown in Table 6, reported ITN use and IPTp uptake were higher among participants of the intervention group compared to the control group at two-months and four-months post-intervention. The control group also reported having a higher incidence of malaria diagnosis than the intervention group at both time points. The mean haematocrit of the intervention group was higher than that of the control group (t (251, 250.72) = 2.649, p = 0.009).
### Table 6
Comparison of reported malaria preventive practices and maternal clinical conditions between the groups, at two months, and four months post-intervention

| Variable                  | Group                      | Fr Eq. (%) |χ² | df | p     |
|---------------------------|----------------------------|------------|----|----|-------|
|                           | Intervention               | Fr Eq. (%) | n = 186 |    |       |
|                           |                           |            |        |    |       |
|                           | Control                    | Fr Eq. (%) | n = 186 |    |       |
|                           |                            |            |        |    |       |
| Reported ITN use          |                            |            |        |    |       |
|                           | Never                      | 38 (22.4)  | 40 (25.2) | 27.974 | 4 | < 0.001 |
|                           | Seldom                     | 11 (6.5)   | 38 (23.9) |    |       |
|                           | Sometimes                  | 32 (18.8)  | 32 (20.1) |    |       |
|                           | Often                      | 51 (30.0)  | 22 (13.8) |    |       |
|                           | Almost always              | 38 (22.4)  | 27 (17.0) |    |       |
| Reported ITN use          |                            |            |        |    |       |
|                           | Never                      | 30 (21.6)  | 35 (27.3) | 12.905 | 4 | 0.012 |
|                           | Seldom                     | 8 (5.8)    | 22 (17.2) |    |       |
|                           | Sometimes                  | 28 (20.1)  | 24 (18.8) |    |       |
|                           | Often                      | 39 (28.1)  | 22 (17.2) |    |       |
|                           | Almost always              | 34 (24.5)  | 25 (19.5) |    |       |
| Reported doses of IPTp taken |                            |            |        |    |       |
|                           | None                       | 24 (14.1)  | 40 (25.2) | 10.609 | 2 | 0.005 |
|                           | One                        | 103 (60.6) | 97 (61.0) |    |       |
|                           | Two                        | 43 (25.3)  | 22 (13.8) |    |       |
| Reported doses of IPTp taken |                            |            |        |    |       |
|                           | None                       | 6 (4.3)    | 10 (7.8)  | 26.350 | 3 | < 0.001 |
|                           | One                        | 20 (14.4)  | 47 (36.7) |    |       |
|                           | Two                        | 82 (59.0)  | 62 (48.4) |    |       |
|                           | Three                      | 31 (22.3)  | 9 (7.0)   |    |       |
| Reported malaria diagnosis |                            |            |        |    |       |
|                           | Yes                        | 76 (46.1)  | 90 (57.7) | 4.345 | 1 | 0.037 |
|                           | No                         | 89 (53.9)  | 66 (42.3) |    |       |
| Reported malaria diagnosis |                            |            |        |    |       |
|                           | Yes                        | 36 (25.9)  | 49 (38.6) | 4.910 | 1 | 0.027 |
|                           | No                         | 103 (74.1) | 78 (61.4) |    |       |
| Haematocrit: mean (SD)    |                            |            |        |    |       |
|                           | Baseline                   | 33.09 (4.00) | 32.42 (3.71) |    |       |
|                           | 2 months                   | 31.93 (4.09) | 30.63 (3.70) |    |       |

Comparison of pregnancy outcomes and birth weights between the groups

Out of the 281 participants from whom post-delivery information were obtained, 257 (91.5%) had hospital deliveries. Also, while four participants had reported having a stillbirth, none had reported
having a miscarriage. The birth weights of 251 babies were retrieved, which ranged from 1.20 to 4.30 kg, with mean (SD) weight of 2.75 (0.60) kg. There was no significant difference between the birth weights of the two groups ($t = 1.894, df = 249, p = 0.059$). There was also no significant difference in the occurrence of still births between groups ($p = 0.623$). Also, 22.2% and 29.6% respectively, of participants in the intervention and control groups had babies with a low birth weight, with no significant differences in the proportion of low birth weight babies between the groups ($\chi^2 = 1.780, df = 1, p = 0.182$).

Table 7
Comparison of the birth outcomes and birth weight categories between the intervention and control groups

| Variables                  | Groups          | \(\chi^2\) | df  | p      |
|----------------------------|-----------------|------------|-----|--------|
|                            | Intervention    |            |     |        |
| FrEq. (%)                  | n = 194         |            |     |        |
| Birth outcome              |                 |            |     |        |
| Live birth                 | 140 (97.9)      |            | 137 | (99.3) |
| Stillbirth                 | 3 (2.1)         |            | 1   | (0.7)  |
| Birth weight category      |                 |            |     |        |
| Normal birth weight        | 98 (77.8)       |            | 88  | (70.4) |
| Low birth weight           | 28 (22.2)       |            | 37  | (29.6) |

Effect of the intervention on reported ITN use and IPTp uptake

Table 8 presents the effects of group, time, and group-time interaction on reported ITN use and IPTp uptake. For both of these variables, the effects of group, time and group-time interaction were all significant.

Table 8
Fixed effects of group, time, and group-time interaction on reported malaria preventive measures

| SOURCE                     | F    | df1 | df2   | Sig.   |
|----------------------------|------|-----|-------|--------|
| Reported ITN use           |      |     |       |        |
| Group                      | 5.90 | 1   | 1062  | 0.015  |
| Time                       | 56.27| 2   | 1062  | <0.001 |
| Group*Time                 | 6.64 | 2   | 1062  | 0.001  |
| Reported IPTp uptake       |      |     |       |        |
| Group                      | 35.26| 1   | 1062  | <0.001 |
| Time                       | 569.70| 2  | 1062  | <0.001 |
| Group*Time                 | 14.27| 2   | 1062  | <0.001 |

Note: Adjustment made for 12 potential confounding variables with missing data replaced

The interaction plot between group and time for reported frequency of ITN use is presented in Fig. 2.

There was an increase in the frequency of ITN use among both the intervention and control groups from baseline to two months post-intervention, followed by a mild downward slope for the
intervention group from two months post-intervention to four months post-intervention. For the control group however, there was a further increase from two months post-intervention to four months post-intervention. As presented in Fig. 3, there was a progressive increase in number of IPTp doses taken from baseline to four months post-intervention for both groups. It can also be seen that after baseline, both reported ITN use and IPTp uptake persistently remained higher for the intervention group compared to the control group.

Figure 2. Interaction Plot between Group and Time for ITN Use. The vertical axis shows the frequency levels of reported ITN use.

Effect Of The Intervention On Haematocrit And Birth Weight

Table 9 presents the effects of group, time, and group-time interaction on some of the studied maternal and foetal variables. For incidence of malaria diagnosis, there was only significant effect for time and not group or group-time interaction. There was significant effect of group and time, and group-time interaction, on haematocrit level. However, there was no significant effect for group, on babies’ birth weights.

### Table 9

| OUTCOME                  | F    | df1 | df2 | Sig.  |
|--------------------------|------|-----|-----|-------|
| Reported malaria diagnosis |      |     |     |       |
| Group                    | 3.67 | 1   | 1062| 0.056 |
| Time                     | 26.04| 2   | 1062| < 0.001|
| Group*Time               | 0.21 | 2   | 1062| 0.808 |
| Haematocrit              |      |     |     |       |
| Group                    | 16.64| 1   | 694 | < 0.001|
| Time                     | 220.37| 1  | 694 | < 0.001|
| Group*Time               | 17.42| 1   | 694 | < 0.001|
| Birth weight             |      |     |     |       |
| Group                    | 1.41 | 1   | 328 | 0.236 |

Note: Adjustment made for 12 potential confounding variables with missing data replaced

Plot of group and time interaction for haematocrit levels is shown in Fig. 4. There were only two time points (baseline and two months post-intervention) between which there was a significant drop in haematocrit levels for both groups.

Magnitude Of The Intervention Effect

Table 10 illustrates the magnitude of the intervention effect in this study. A participant in the intervention group reportedly slept under an ITN by an additional 0.32 more levels, and took 0.37
more doses of IPTp than a participant in the control group. A participant in the intervention group also achieved a haematocrit level of 0.80% above a participant in the control group. There were no significant differences in incidence of malaria diagnosis, as well as babies’ birth weights between the two groups.

Table 10
Fixed coefficients of the outcome variables

| Variable                  | Coefficient | Sig.    | 95% C.I. |
|---------------------------|-------------|---------|----------|
|                           |             |         | Lower    | Upper    |
| Reported ITN use          |             |         |          |          |
| Intervention             | 0.32        | 0.018   | 0.06     | 0.59     |
| Control                  | 0           |         |          |          |
| Reported IPTp uptake      |             | < 0.001 | 0.26     | 0.47     |
| Intervention             | 0.37        |         |          |          |
| Control                  | 0           |         |          |          |
| Reported malaria diagnosis|             | 0.213   | -0.450   | 0.100    |
| Intervention             | -0.18       |         |          |          |
| Control                  | 0           |         |          |          |
| Haematocrit              |             |         |          |          |
| Intervention             | 0.80        | < 0.001 | 0.53     | 1.07     |
| Control                  | 0           |         |          |          |
| Birth weight             |             |         |          |          |
| Intervention             | 0.08        | 0.236   | -0.05    | 0.22     |
| Control                  | 0           |         |          |          |

Note: Adjustment made for 12 potential confounding variables with missing data replaced

Sensitivity Analysis

Table 11 presents the results of Generalized Linear Mixed Models analysis without replacing missing values. The effect of group on malaria and birth weight were now significant.

Table 11
Fixed effects of group, time, and group-time interaction on the outcome variables

| SOURCE                    | F     | df1 | df2 | Sig.   |
|---------------------------|-------|-----|-----|--------|
| Reported ITN use          |       |     |     |        |
| Group                     | 10.08 | 1   | 914 | 0.002  |
| Time                      | 47.22 | 2   | 914 | <0.001 |
| Group*Time                | 8.17  | 2   | 914 | <0.001 |
| Reported IPTp uptake      |       |     |     |        |
| Group                     | 8.80  | 1   | 914 | 0.003  |
| Time                      | 410.81| 2   | 914 | < 0.001|
| Group*Time                | 4.24  | 2   | 914 | 0.015  |
| Reported malaria diagnosis|       |     |     |        |
| Group                     | 7.92  | 1   | 905 | 0.005  |
| Time                      | 22.46 | 2   | 905 | < 0.001|
| Group*Time                | 1.04  | 2   | 905 | 0.354  |
| Haematocrit               |       |     |     |        |
| Group                     | 15.68 | 1   | 526 | < 0.001|
| Time                      | 162.75| 1   | 526 | < 0.001|
| Group*Time                | 17.38 | 1   | 526 | < 0.001|
| Birth weight              |       |     |     |        |
| Group                     | 7.69  | 1   | 207 | 0.006  |

Note: Adjustment made for 12 potential confounding variables with missing data NOT replaced
A comparison of the fixed coefficients for group, with, and without replacement of missing values is presented in Table 12. The effect of the intervention on IPT uptake and haematocrit were negatively affected by drop out, while drop out had a positive impact on the other variables.

Table 12
Comparison of fixed coefficients for group, with and without imputed missing values

| Variable                  | Missing values not imputed | Missing values imputed | Coefficient difference | Percentage coefficient difference |
|---------------------------|---------------------------|------------------------|------------------------|----------------------------------|
|                           | Coefficient               | Sig.                   | Coefficient            | Sig.                            |
| Reported ITN use          |                           |                        |                        |                                 |
| Intervention              | 0.50                      | 0.003                  | 0.32                   | 0.018                           | 0.18                             | 5.63                             |
| Control                   | 0                         |                        |                        |                                 |                                   |
| Reported IPTp uptake      |                           |                        |                        |                                 |                                   |
| Intervention              | 0.23                      | < 0.001                | 0.37                   | < 0.001                         | -0.14                            | -37.84                           |
| Control                   | 0                         |                        |                        |                                 |                                   |
| Reported malaria diagnosis|                           |                        |                        |                                 |                                   |
| Intervention              | -0.432                    | 0.014                  | -0.18                  | 0.213                           | -                                | -                                 |
| Control                   | 0                         |                        |                        |                                 |                                   |
| Haematocrit               |                           |                        |                        |                                 |                                   |
| Intervention              | 0.75                      | < 0.001                | 0.80                   | < 0.001                         | -0.05                            | -6.25                            |
| Control                   | 0                         |                        |                        |                                 |                                   |
| Birth weight              |                           |                        |                        |                                 |                                   |
| Intervention              | 0.22                      | 0.006                  | 0.08                   | 0.236                           | -                                | -                                 |
| Control                   | 0                         |                        |                        |                                 |                                   |

Discussion

A single health education session (based on the IMB model) on malaria prevention during pregnancy was implemented to determine its effectiveness in improving malaria preventive practices and pregnancy outcomes among pregnant women. At the end of the study, reported ITN use, IPTp uptake, and haematocrit levels, were significantly higher among those in the intervention group compared to the control group. However, there was no significant difference in the incidence of reported malaria diagnosis, and babies’ birth weights between the two groups. The proportion of participants who completed the study (71.8%), was lower than that for a previous prospective study conducted among pregnant women in Maiduguri (83.3%) by Bako et al. [16]. This was probably so because the previous study was conducted in a tertiary hospital, and as such, more likely to have had more compliant clients. The aftermath of the Boko Haram insurgency which has been characterized by massive displacements and huge socio-economic loses to the region [24] could also have contributed to some of the attrition in this study. The participants also showed a very poor knowledge of their last menstrual periods, which could be explained by the low level of education and/or poor attitude.
towards the dates, as even many who were educated up to tertiary levels, did not know theirs.
The results of the behavioural outcomes could be interpreted at a group-level to mean that for 32% of the participants, an individual in the intervention group is expected to sleep under an ITN, a level more frequently; while for 37% of the participants, an individual in the intervention group is expected to take one more dose of IPTp compared to an individual in the control group. From the interaction plot between group and time for frequency of ITN use and IPTp uptake, it could be concluded that the intervention was effective in improving the two outcome variables. Seasonal variation in malaria prevalence has been reported in Maiduguri, with the highest prevalence in September, followed by June, and the least prevalence in March [59]. Seasonal variation has also been reported in mosquito population and mosquito biting habit in other parts of Nigeria [60, 61]. Considering that the selection of participants as well as baseline data collection was concluded in March, the increase in ITN use with time among those in the control group could be explained by the increase in mosquito presence during the study period. However, the effect of the intervention is likely to have led to a higher ITN use among the intervention group.

At the second follow-up visit, the control group reported a similar IPTp uptake (7.8% had none, 36.7% had once, 55.4% had twice or thrice), comparable to that from a cohort study at a tertiary health centre in Maiduguri (20.0% had none, 23.8% had once, 56.2% had twice) [18]. Since the control group had received only a placebo intervention, their results should be expected to be comparable to participants in a cohort study who had received no intervention at all. However, overall in Borno state, lower levels of uptake had been reported (13.9% had once, 6.7%, had twice, 1.9% had thrice) [23]. This generally lower uptake in the state was probably because over a half of them had not attended antenatal care, which is an important factor for IPTp receipt [62]. Also, although some previous interventions had been effective in increasing malaria preventive practices among the intervention groups [27, 42, 63, 64], the intensity of such interventions in terms of duration, had been contrastingly very high (as some lasted for up to a month) when compared to the single session four-hour intervention in this study.

Around a third of the respondents (30.5%) reported that they had never been diagnosed of malaria
during their current pregnancies, 47.6% reported having one episode, 18.7% had two, while 3.2% had had malaria up to three times during their pregnancies. These findings appear very similar to fin, among women from selected communities in Badagry, Nigeria, where 36.0% reported that they had suffered malaria only once, 18.0% twice, 6% thrice, while 36% had never had malaria during their pregnancies [65]. Even though both groups showed a similar trend of initial increase, followed by a decrease in the incidence malaria diagnosis, it had consistently been higher among the control group since after baseline. Cohee et al. [66] had reported in a previous study, that IPTp was not effective in preventing incident cases of malaria, but rather decreasing the prevalence of those already infected.

As such, a higher rate of progression from asymptomatic to symptomatic malaria should be expected in the control group, since the intervention group had a higher IPTp uptake, even though not statistically significant.

Haematocrit measurements for only two time points (baseline and first follow-up) were only obtained. Both groups had experienced a significant decline in their mean haematocrit levels from baseline to the time of their first follow-up visits. This decline in haematocrit with advancing pregnancy is consistent with earlier findings, and has been attributed to haemodilution [67, 68]. However, while there were no significant differences between the groups at baseline, the mean haematocrit level for the intervention group was higher than that for the control group at their first follow-up visit. Attrition also had no effect on the effect size of the intervention on haematocrit, as it remained the same even after replacing missing values.

The incidence of low birth weight was higher than previous findings of 7.8% and 16.9% in hospital-based cohort studies in Maiduguri [16, 22]. Overall prevalence of low birth weight in Nigeria was also lower than findings of this study (7.3%) [66]. Lower socio-economic status [69-72] has been associated with the occurrence of low birth weight, which could have probably been the reason for the higher incidence of low birth weight in this study. This presumed lower social status of participants of this study could be inferred from the hospital type (secondary versus tertiary level), and the presence of IDPs among the participants. Malaria infection during pregnancy has been associated with low birth weight [10, 73] and as such, since the intervention was not significant in reducing the incidence of
malaria, no significant effect would therefore be anticipated for babies’ birth weights.

The stillbirth rate of 14/1000 deliveries, in this study, was slightly lower than findings from a four-year study at a tertiary hospital in Maiduguri where 22 stillbirths were reported, per 1,000 deliveries. Even in a tertiary hospital in eastern Nigeria, 18.0% (180 per 1,000) of the deliveries had ended in a stillbirth [74]. A likely explanation for the low stillbirth rates and zero miscarriage in this study, could have been a demoralization on the part of those who had had those experiences, which made them drop out of the study, leading to loss of subsequent information.

An adequate number of participants had been recruited into the study since their number was above the minimum required sample size, calculated. Among other strengths of the study were the random allocation of participants to groups; the placebo intervention given to the control group on a relevant topic like breast feeding; blinding of the participants and assessors; development of a standard module in the target language, and having had all sessions for both groups delivered by the same facilitator. The robust generalized-linear mixed models analysis was also likely to allow for visualization of the pure effects of the intervention. There was no significant difference in attrition between the intervention and control group. The baseline characteristics of those who dropped out and those who remained in the study were also the same, suggesting that attrition was unlikely to have affected the randomization process. In addition, the intention to treat and sensitivity analysis ensured that the randomization was preserved, and allowed for assessing the impact of attrition on the results, respectively. This similarity of age range, ages at first marriage, and family type of participants’ in this study with that of respondents in the Demographic and Health Survey of 2013 [23] suggests the possibility of a wider generalization of its results.

A major limitation of this study was that the dependent variables (except haematocrit and birth weight) were measured based on self-reporting, rendering the results less accurate against if they were obtained from direct observation [75]. Reported net use for example, suggests that the person has been in the net all though the night, which may not necessarily be so. Outdoor activities at night [76], multiple exits and entries, with lifting of the nets at night [77], and entering the nets late, are factors which could greatly affect the level of protection given by the net. These are however not
captured in this study, as such making it impossible to accurately compare the protection received from insecticidal nets by the two groups. Malaria infection, which was also measured based on self-reporting, was also prone to bias from individuals’ characteristics such as the level of infection (clinical or sub-clinical) and also their level of stoicism. Another limitation of the study was the possibility of contamination from information sharing at home or other meeting places. Attrition of some participants means that there is the possibility that the results obtained are not a hundred percent accurate, since information from some of the participants were not actually measured, but approximated. With the major ethnic group in Maiduguri being Kanuri, implementation of the intervention module may be limited in certain parts of the city where Hausa language is poorly understood.

Conclusion
The intervention was effective in improving reported ITN use, IPTp uptake, and haematocrit levels. It is thus recommended that the module be adopted and incorporated into the routine ante-natal care programmes. This could mean creating an extra day visit for the attendees, so that the contents of the module can be adequately covered. Considering participants’ low level of knowledge of their menstrual period, it is recommended for future studies to adopt the use of early ultrasound scanning to measure the gestational ages. Malaria infection should also be tested using microscopy for malaria parasite, rather than relying on self-reporting which may not be accurate. Further studies should also device effective tracking systems to trace drop outs, so as to minimize the attrition rates.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained to carry out the research, from the Ethics Committee for Research Involving Human Subjects of the Universiti Putra Malaysia (UPM) (UPM/TNCPI/RMC/1.4.18.2 (JKEUPM). Permission was also obtained from the Ethics Committee of the State Specialist Hospital, Maiduguri (SSH/GEN/64/Vol.1). The study was then registered with the Pan African Clinical Trials Registry (PACTR201610001823405). A respondent’s information sheet in Hausa language was provided to each participant, from whom informed consent was obtained, after they had been taken through it,
before their participation in the study.

**Availability of data and material**

The data set for this study are available as supplementary material.

**Clinical Trial Registration**

The trial was also registered with the Pan African Clinical Trial Registry (PACTR201610001823405), on 26 October 2016. http://apps.who.int/trialsearch/Trial2.aspx?TrialID=PACTR201610001823405

**Consent to publish**

The authors have given their full consent to the journal to publish this work.

**Competing interests**

The authors declare that they have no competing interests.

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**Author’s contributions**

AB and SS conceived the study. AB, SS, NZ, NB and BA participated in the study design and manuscript review. AB and SS did the data analysis and manuscript writing. All authors read and approved the final manuscript.

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Figures
Consort Flow Chart of Intervention and Control Groups

Figure 1

Assessed for eligibility (n=521)

Excluded (n=149)
- Not meeting inclusion criteria (n=142)
- Declined to participate (n=7)

Randomized n=372

Allocated to IMB intervention group n=186
- Received health educational intervention on malaria (n=151)
- Did not receive allocated intervention (unable to attend) (n=35)

Allocated to control group n=186
- Received health education on breast feeding (n=159)
- Did not receive allocated intervention (unable to attend) (n=27)

FOLLOW-UP

- 170 still present
- total loss to follow-up (could not ascertain the reason(s)) (n=16)

FOLLOW-UP

- 159 still present
- total loss to follow-up (could not ascertain the reason(s)) (n=27)

FOLLOW-UP

- 139 present
- total loss to follow-up (could not ascertain the reason(s)) (n=47)

FOLLOW-UP

- 128 still present
- total loss to follow-up (could not ascertain the reason(s)) (n=58)

Analysis

Analysed (n=186)
(Intention-to-treat)
Figure 2

Interaction Plot between Group and Time for ITN Use. The vertical axis shows the frequency levels of reported ITN use.
Figure 3

Interaction Plot between Group and Time for IPTp Use. The vertical axis illustrates the number of reported IPTp doses taken.
Figure 4

Interaction Plot between Group and Time for Haematocrit. The vertical axis presents the haematocrit levels in percentage.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

Data set RCT Mal J.xlsx