# Effect of a congregation-based intervention on uptake of HIV testing and linkage to care in pregnant women in Nigeria (Baby Shower): a cluster randomised trial

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## Summary

**Background** **Few effective community-based interventions exist to increase HIV testing and uptake of antiretroviral therapy (ART) in pregnant women in hard-to-reach resource-limited settings. We assessed whether delivery of an intervention through churches, the Healthy Beginning Initiative, would increase uptake of HIV testing in pregnant women compared with standard health facility referral.**

**Methods** **In this cluster randomised trial, we enrolled self-identified pregnant women aged 18 years and older who attended churches in southeast Nigeria. We randomised churches (clusters) to intervention or control groups, stratified by mean annual number of infant baptisms (<80 *vs* ≥80). The Healthy Beginning Initiative intervention included health education and on-site laboratory testing implemented during baby showers in intervention group churches, whereas participants in control group churches were referred to health facilities as standard. Participants and investigators were aware of church allocation. The primary outcome was confirmed HIV testing. This trial is registered with ClinicalTrials.gov, identifier number NCT 01795261.**

**Findings** **Between Jan 20, 2013, and Aug 31, 2014, we enrolled 3002 participants at 40 churches (20 per group). 1309 (79%) of 1647 women attended antenatal care in the intervention group compared with 1080 (80%) of 1355 in the control group. 1514 women (92%) in the intervention group had an HIV test compared with 740 (55%) controls (adjusted odds ratio 11·2, 95% CI 8·77–14·25; p<0·0001).**

**Interpretation** **Culturally adapted, community-based programmes such as the Healthy Beginning Initiative can be effective in increasing HIV screening in pregnant women in resource-limited settings.**

**Funding** **US National Institutes of Health and US President's Emergency Plan for AIDS Relief.**



## Introduction

Sub-Saharan Africa has the highest burden of HIV/AIDS in the world. Although countries in sub-Saharan Africa account for 13% of the world population, they are home to 71% of people living with HIV worldwide. Owing to a plethora of biological, cultural, and economic factors, women are disproportionately affected by HIV and represent more than half of all adults living with HIV in sub-Saharan Africa.[1]

Although mother-to-child transmission of HIV has almost been eliminated in many high-income countries, it is an important source of new HIV infection in sub-Saharan African countries. According to the 2014 report of the Joint United Nations Programme on HIV/AIDS (UNAIDS),[1] sub-Saharan Africa accounted for 87% of the 1·5 million pregnant women living with HIV and 91% of children living with HIV worldwide. Despite improved effort and the availability of simple, relatively inexpensive, and highly effective antiretroviral regimens for prevention of mother-to-child transmission of HIV (PMTCT), 32% of pregnant women did not receive antiretroviral therapy (ART) for PMTCT in 2014, resulting in an estimated 210 000 new infections in children.[1]

Nigeria is one of 21 priority countries in sub-Saharan Africa that, together with India, accounts for 90% of pregnant women infected with HIV. In 2013, Nigeria had an HIV testing rate of less than 20% in pregnant women and accounted for 26% of all new infections in children in the 21 countries.[1–3] Identification of HIV-infected pregnant women through routine HIV screening is a crucial step needed to initiate interventions designed for PMTCT. At present, most pregnant women access clinics through the health-care system to undertake HIV screening and receive available PMTCT interventions. Such a clinic-based approach is challenging when only 35% of deliveries occur in hospitals and only 2·9% of health-care facilities have effective PMTCT programmes.[4] Thus, finding new approaches to translate evidence-based interventions in PMTCT to sustainable community-based programmes is imperative to realise the WHO/the US President's Emergency Plan for AIDS Relief (PEPFAR) goal of eliminating new paediatric HIV infections by 2015.[2]

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See **Comment** page e657

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## Research in context

### Evidence before the study

We searched PubMed, Ovid MEDLINE, Web of Science, the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials, and Database of Abstracts of Reviews on Effects for articles published between Jan 1, 2000, and Dec 31, 2014, on community-based (including congregation or faith-based) interventions to increase HIV testing in pregnant women. To maximise sensitivity, we did not use any methodological filters in the initial search and used the following broad MeSH terms "adult", "pregnancy", "women", "HIV testing", "barriers to PMTCT", "Africa south of the Sahara", "female", "HIV infections/prevention & control", "HIV infections/transmission", "prenatal diagnosis/statistics & numerical data", "prenatal care/statistics & numerical data", "prenatal care/statistics & numerical data", and "counseling/methods". We narrowed our search in the identified articles using the search terms "HIV", "HIV-exposed infants", "case finding", "children", "community health workers", "linkage to care", "pediatrics", "community-based interventions", "faith-based interventions", "church; congregation", and "HIV screening and HIV testing". We examined systematic reviews and meta-analyses and other articles that met the following selection criteria: randomised controlled trials, cluster randomised controlled trials, controlled clinical trials, controlled before-and-after studies, and interrupted time series studies that investigated the comparative effects of community-based interventions to increase HIV testing in pregnant women versus other approaches. Our clinical librarian ran the searches, two authors selected studies, assessed methodological quality, and extracted data. Disagreements were resolved by repeated review, discussion, and consensus of all authors.

Williams and colleagues did a review of congregation-based programmes to address HIV/AIDS: elements of successful implementation, published in 2011. Williams and colleagues identified early involvement of the congregation during both design and implementation as a major key factor to success. Gulaid and colleagues published another review on promising practices in community engagement for the elimination of new HIV infections in children in 2012. Evidence from this review shows that increased engagement with community and faith-based organisation that is participatory is needed for an effective outcome. Similarly, Marcos and colleagues published a review on community strategies to improve care and retention along the prevention of mother-to-child transmission of HIV (PMTCT) cascade in 2012 in which they found nine articles that documented statistically significant improvement in key HIV prevention strategies including HIV testing. None of these studies used a randomised and controlled design. In July, 2013, Suthar and colleagues published a systematic review and meta-analysis of community-based approaches, which concluded that interventions such as cash transfers, home-based testing, and mobile testing were effective in promoting uptake of HIV testing. Suthar and colleagues concluded that some of the major challenges with these approaches have been the absence of several testing opportunities and losses to follow-up after testing and sustainability. More importantly, despite the wide availability of congregation centres and faith-based organisations (including churches, mosques, and other worship centres) in many resource-limited settings, few experimental studies have compared such avenues for testing with health facilities that are often unavailable in hard-to-reach communities. Suthar and colleagues offer many opportunities for testing and follow-up.

### Added value of this study

HIV counselling and testing is an important entry point for most forms of HIV prevention and control including PMTCT. Although barriers to HIV testing have been identified at the patient, provider, and health systems levels, barriers at the health system level have been identified to have the most adverse effect on HIV testing in pregnant women. Although several studies have tested the effectiveness of single interventions on uptake of HIV testing in pregnant women, few randomised studies have tested a framework that identified pregnant women early, implemented an intervention with an integrated testing approach (HIV plus other conditions to reduce stigma associated with HIV-only test approaches), and used a systematic follow-up mechanism.

### Implications of all the available evidence

Findings from this study show that, as the US President's Emergency Plan for AIDS Relief (PEPFAR) shifts its emphasis from an emergency response to a country-owned approach, countries will need to build on existing socially accepted community-based infrastructures to implement culturally adapted, community-driven, and sustainable approaches that can substantially reduce HIV transmission and diminish its public health importance in low-income countries. Nigeria is one of 22 countries that account for 90% of pregnant women living with HIV and is one of only four in these countries with an HIV testing rate of less than 25% in pregnant women. Nigeria alone accounted for 26% of new child infections in 2013. There is a dearth of community-based interventions targeted at this problem in countries with very low HIV testing rate in pregnant women.

Ranked highly among 53 other nations in church attendance, Nigeria has an extensive network of faith-based institutions, and faith plays an important part in the social life of Nigerians. Religious leaders in Nigeria are knowledgeable about HIV and can harness their position for HIV prevention.[5–7] Building on this background, we developed the Healthy Beginning Initiative (HBI), a culturally adapted, family-centred approach that relies on the widely distributed religious infrastructure and church-based community networks to promote individual testing, tracking, and retention of participants.

We did a cluster randomised trial of 40 churches in southeast Nigeria. We considered randomising each patient, but the likelihood of contamination posed a threat to internal validity; thus, individual pregnant women were nested within the church. The communities where the churches were located had similar ethnic group composition, culture, language, and church attendance. We also considered a crossover design, but the possibility of withdrawing an intervention if it was effective would make this design problematic. We aimed to identify whether pregnant women randomised to the intervention would have a higher rate of HIV testing and receipt of ART than those randomised to the control group.

## Methods

### Trial design and participants

We did a two-arm cluster randomised trial in Enugu State in southeast Nigeria, designed to assess the effect of a congregation-based HBI that provided free, integrated on-site laboratory tests during a church-organised baby shower (a reception held in honour of a pregnant woman where she plays pregnancy-related games and receives gifts from friends, usually, items she would need during delivery or immediately after birth) as the intervention group versus a clinic-based referral approach as the control group on the rate of HIV testing and receipt of ART in pregnant women.

We selected Enugu State in southeast Nigeria for several reasons. First, its population is culturally and ethnically homogeneous and predominately Christian, with church attendance approaching 90%.[5,6] Second, the overall state's HIV seroprevalence of 5·1% is close to the national average of 4·1%. Third, the participating churches were widely distributed and represented variations in the prevalence rate of HIV across the state of 4–8% (mean 6%).

Randomisation was done at the level of the churches (clusters) and individuals were recruited from the congregations.

We assessed 200 churches and collected data on infant baptism for the 3 years preceding this study (2010, 2011, and 2012). Infant baptism was used as an indirect measure of the potential number of pregnant women in the churches. Churches eligible for randomisation must have had at least 20 infant baptisms every year for the past 3 years. In most cases, we selected one church in each community to maintain a distance between participating sites. Most of the communities were at least 5 km apart with some as far as 20 km (12·5 miles) apart. For some churches assessed but not selected because of their small size (fewer than 20 baptisms per year) but in close proximity to a selected site (and most times with the same pastor as the primary site), pregnant women were allowed to participate in the HBI through the primary sites. These women were included in the total number of women randomised since they were recruited through the primary sites. Self-identified pregnant women 18 years or older who attended any of the study sites were eligible to participate. Women were encouraged to participate with their male partners, but could still participate if their male partner chose not to take part.

Every Sunday, the priest asked pregnant women and their male partners in the congregation to step to the altar for prayers. He prayed for a healthy pregnancy, successful delivery, and encouraged pregnant women to seek care at a health facility during their pregnancy. He introduced HBI and the study team as a programme supporting pregnant women in the congregation during pregnancy and described the programme's objectives. Pregnant women and their male partners were encouraged to participate.

We focused on a congregation-based intervention because such interventions have been used effectively in health promotion in communities in which faith has a substantial role, such as Nigeria, with 87% of people reporting religious service attendance at least once a week.[5,6,8–12] Faith-based organisations are already involved in general HIV education and awareness in Nigeria and their role increased with implementation of the 2010–15 National Strategic Framework.[7,13,14]

For this cluster randomised trial, the funding agencies mandated that we have a local PEPFAR-supported partner working in the area of the proposed research. Our local partner, Prevention, education, treatment, Training and Research-Global Solutions (PeTR-GS), working with Sunrise Foundation, a local non-governmental organisation, did training workshops for all study staff and church-based volunteer health advisers. The organisations received training on the study protocol, including how to obtain informed consent, data collection forms, and confidentiality. Additionally, study staff received information on HIV counselling, delivery of HIV test results, and post-test counselling. Although priests were not actively involved in the main intervention, they received basic information on HIV transmission, mother-to-child transmission, PMTCT, and HIV counselling methods.

This study was approved by the Institutional Review Board of the University of Nevada, Reno, and the Nigerian National Health Research Ethics Committee.

### Randomisation and masking

Recruitment occurred at the level of the churches and then participants, whereas randomisation occurred only at the church level. Churches were selected and ranked according to size on the basis of mean annual number of infant baptisms (as a proxy for the number of pregnant women) and randomly assigned to either the intervention group or the control group. Randomisation of churches occurred 1:1 in four cohorts of ten churches after the ranking order (largest to smallest), stratified by number of infant baptisms (<80 *vs* ≥80). Assignment of smaller churches to the closest coordinating churches was pre-specified to avoid random assignment by participants.

The sequence of randomisation was generated by the study biostatistician (WY) and kept in a sealed opaque envelope away from the study sites.[17] Once the sites were recruited and baseline information on churches collected (eg, type and size of congregation), the sites were informed of their randomisation group and assigned a code. Participants followed the randomisation of the church they attend. Because of the nature of the intervention, it was impossible to mask the participants, community health nurses, volunteer health advisers, and study coordinators to the group assignment.

### Procedures

For participants in churches randomised to the intervention group, baby showers were held one Sunday every month. Free integrated laboratory tests were offered to pregnant women during the baby shower, including tests for haemoglobin, malaria, sickle-cell genotype, HIV, hepatitis B, and syphilis. This integrated testing was designed to reduce stigma associated with HIV-only testing. Participants were provided with information on the six conditions included in the integrated tests and also received a Mama Pack provided by the church and distributed by their male partner or by the clergy. The Mama Pack contained basic essentials for a pregnant woman during delivery, including sanitary pads, a clean razor blade, alcohol, and gloves. The pack was given to all participating pregnant women bearing in mind that less than 50% of them would deliver in a health facility. Women identified as HIV-positive were linked to PeTR-GS's comprehensive HIV programme. One advantage of this approach was avoidance of duplicate testing by providing copies of HIV test results to participants to make available to staff at health facilities where they attended prenatal care. On-site HIV testing data and health facility data were used to confirm HIV testing and receipt of ART for participants in intervention churches.

Participants completed a post-delivery questionnaire to ascertain and document HIV testing during pregnancy and pregnancy outcome at a baby reception held every 2–3 months (pregnant women only needed to attend the reception once after giving birth) to celebrate births with baby gifts and refreshments. The reception also provided an opportunity for follow-up with women needing ongoing care post delivery.

Prayer sessions, baby showers, and baby receptions were done in churches randomised to control groups similar to churches in intervention groups with the exception that the intervention (health education on health conditions and on-site integrated laboratory testing) was not provided during baby showers. Participants in control group churches were encouraged to attend prenatal care at the health facilities where they had access to HIV testing, as is the usual practice. The health facilities were partners in the research through collaboration with our local PEPFAR-supported partner PeTR-GS. Participants completed an investigator-administered questionnaire to collect information on HIV testing and were asked to bring copies to research staff. Participants in control churches were made aware that their laboratory tests would be confirmed with health facilities.

Participants in both intervention and control groups received three study visits: one at baseline (recruitment), one during the baby shower, and one at 6–8 weeks after delivery for the baby reception.

### Outcomes

The primary outcome was confirmed HIV testing during pregnancy. This outcome was selected to determine the difference in HIV testing between the intervention and control groups and define the predictors for such testing. HIV testing in women in churches randomised to the control group were confirmed at the health facility where pregnant women reported prenatal care. Although we were aware of the potential limitations with confirming HIV test results at health facilities, we were also conscious of the unreliability of self-reported testing. In view of our confidence in our ability to confirm most HIV tests done at surrounding health facilities, we chose to use confirmed HIV test for both groups as the primary outcome measure.

The secondary outcomes were rate of PMTCT completion in HIV-infected pregnant women measured by linkage to care and receipt of ART for HIV-infected pregnant women, and the rate of HIV testing in male partners.

### Statistical analysis

Two important sample size estimates were used. The first was the number of pregnant women, and the second was the number of churches, with the pregnant women nested within the churches. Power calculations were done using the PASS 11 module titled inequality tests for two proportions in a cluster randomised design, which implements the methods of Donner and Klar.[15] This power calculation module estimates power for simple two-sample binomial tests for data collected in clusters with non-zero intra-cluster correlation (ICC). With ICC at 0·10, we would need a sample size sufficient to recruit at least 140 women infected with HIV. After considering factors such as HIV prevalence rate and dropout rate in women, the sample size designed was roughly 2700 total pregnant women (1350 per group). A detailed sample size calculation and analysis plan has been described previously.[16]

Our hypothesis test for differences in two binomial proportions at follow-up and data were analysed with the $\chi^2$ test and $t$ tests. The $\chi^2$ statistic was used to assess differences in HIV-test proportions. Student's $t$ test was used to assess differences in continuous data. Multilevel analysis generalised linear mixed models (GLIMMIX) were implemented with that procedure with a logit link function and the binomial distribution. These models are multilevel, allowing incorporation of covariates and confounders for the individual level (such as age, education

level, and previous HIV testing) and cluster level (church) covariates and confounders, such as size of church and congregation type (Anglican or Catholic). Adjusted odds ratios (aORs) between HIV-tested and HIV-non-tested women were obtained by controlling the previously mentioned covariates and potential confounding factors. All analyses were done with SAS version 9.4 and statistical significance was set as $p<0·05$. This trial is registered with ClinicalTrials.gov, identifier number NCT 01795261.

### Role of the funding source

The funding agencies of the study had no role in the study conception, design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication. All authors vouch for the completeness and accuracy of data and data analyses and for the fidelity of the study to the protocol.

## Results

We began enrolment on Jan 20, 2013, and completed it by Sept 29, 2013. Follow-up of enrolled participants was completed on Aug 31, 2014. Of 200 churches assessed for eligibility, we selected 40 on the basis of being centrally located in the community and having at least 20 infant baptisms every year for the past 3 years. 20 were randomly assigned to the intervention group and 20 to the control group. An additional 44 smaller churches close to coordinating intervention churches were assigned to the intervention group and an additional 23 smaller churches close to coordinating control churches were assigned to the control group via a spoke and wheel approach. Of the 3047 pregnant women enrolled across the 40 churches and their linked satellite churches, 45 participants were excluded from the final analysis (figure). 19 women were of conflicting age in the predelivery and post-delivery questionnaire, suggesting that they were younger than the study required age of 18 years. Thus, 3002 enrolled participants were included in the final analysis (figure). Results showed that the observed ICC was 0·14, which suggests that clustering effects existed and parishioners within the same church could be expected to show correlations. Therefore, GLIMMIX procedures with logit link function and binomial distribution were implemented using a logit link function and the binomial distribution.

In general, participants from both control and intervention groups had similar demographics, including family size, marital status, number of previous pregnancies, antenatal care attendance during pregnancy, and distance to the nearest health facility (table 1). Some demographic factors differed significantly. For example, the control group were slightly older than the intervention group, and were more likely to have tertiary-level education, be in full-time employment, reside in urban areas, and have previously tested for HIV.

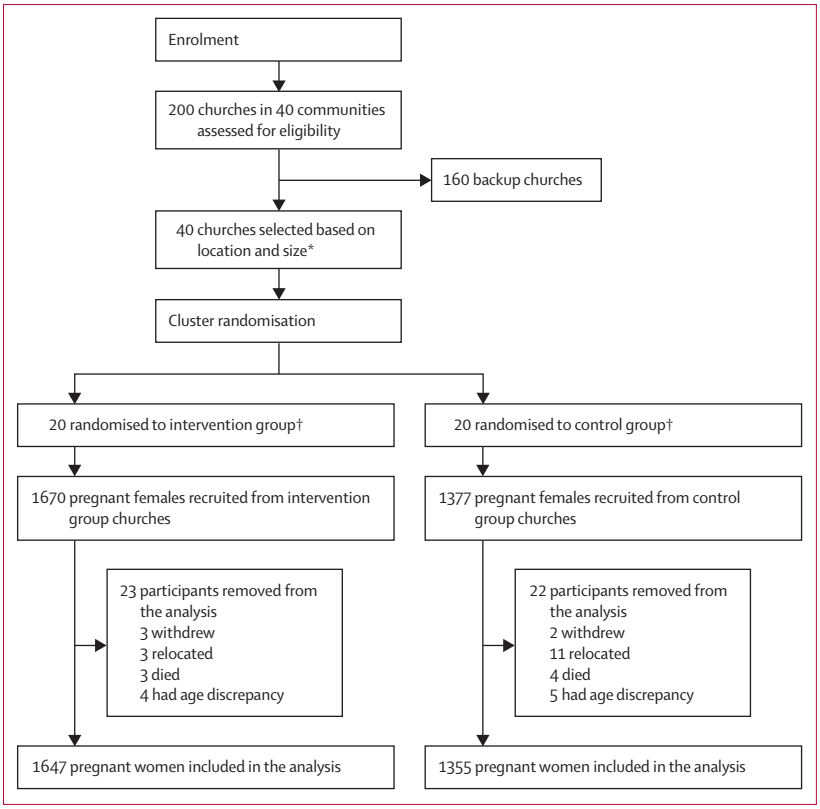


***Figure:*** **Trial profile**
*Selected church has to be centrally located in the community and had at least 20 infant baptisms done each year for the past 3 years. †Additional 44 smaller churches close to coordinating churches were assigned to intervention group and an additional 23 smaller backup churches close to coordinating churches were assigned to control group. These smaller churches follow the randomisation group of the main coordinating church using a spoke and wheel approach.

Table 2 shows rates of HIV testing between control group and intervention group, and between related factors. 1514 (92%) of 1647 pregnant women in the intervention group had an HIV test compared with 740 (55%) of 1355 in the control group. Factors associated with having significantly higher HIV testing rate were full-time or part-time employment compared with unemployment, age younger than 35 years at first pregnancy, and low number of previous pregnancies.

Table 3 shows the odds ratios after adjustment for all demographic factors and other potential predictors for having no HIV testing in pregnant women, so we can determine factors that were barriers to testing. We wanted to present the group at risk (not being tested) in order to locate the target population for the intervention in the future. The odds of pregnant women not being HIV tested were 11 times higher in the control group than in the intervention group (aOR 11·18, 95% CI 8·77–14·25; $p<0·0001$) after controlling for age, educational level, employment, area of residence, age at first pregnancy, number of previous pregnancies, and a history of previous HIV testing. Other significant or marginally significant factors for not getting an HIV test include unemployment, older age at first birth,

high number of previous births, and no previous HIV testing.

73 (2%) of 3002 women in this study had a positive HIV test (table 4) and thus we did not reach the expected level of 140 HIV-positive pregnant women. Prevalence of HIV did not differ between groups. Women in the intervention group were more likely to be linked to care before delivery than were those in the control group (OR 6·2, 95% CI 2·14–18·25; p<0·0001) and were more

| | Intervention group (n=1647) | Control group (n=1355)* | Total (n=3002) |
|---|---|---|---|
| Mean (SD) age (years) | 29·3 (5·9) | 29·7 (5·8) | 29·7 (5·8) |
| Age group (years) | | | |
| 16–24·9 | 377 (23%) | 288 (21%) | 665 |
| 25–34·9 | 962 (58%) | 831 (61%) | 1793 |
| ≥35 | 283 (17%) | 235 (17%) | 518 |
| Marital status | | | |
| Divorced | 0 | 2 (0·15%) | 2 |
| Married | 1531 (93%) | 1278 (94%) | 2809 |
| Separated | 8 (0·5%) | 7 (0·5%) | 15 |
| Single | 108 (7%) | 68 (5·02%) | 176 |
| Education level | | | |
| None or primary | 448 (27%) | 330 (24%) | 778 |
| Secondary | 950 (58%) | 741 (55%) | 1691 |
| Tertiary | 235 (14%) | 277 (20%) | 512 |
| Employment | | | |
| Full-time | 573 (35%) | 506 (37%) | 1079 |
| Part-time | 401 (24%) | 270 (20%) | 671 |
| Unemployed | 632 (38%) | 567 (42%) | 1199 |
| Number of people in family | | | |
| ≤2 | 257 (16%) | 227 (17%) | 484 |
| 3–6 | 1135 (69%) | 935 (69%) | 2070 |
| ≥7 | 220 (13%) | 179 (13%) | 399 |
| Distance to health facility | | | |
| 0–5 km | 529 (32%) | 486 (36%) | 1015 |
| 5–10 km | 629 (38%) | 520 (38%) | 1149 |
| 10–15 km | 295 (18%) | 211 (16%) | 506 |
| >15 km | 172 (10%) | 121 (9%) | 293 |
| Residency area | | | |
| Rural | 1276 (77%) | 880 (65%) | 2156 |
| Urban | 356 (22%) | 466 (34%) | 822 |
| Age at first pregnancy (years) | | | |
| <24·9 | 1044 (63%) | 805 (60%) | 1849 |
| 25–34·9 | 489 (30%) | 474 (35%) | 963 |
| ≥35 | 17 (1%) | 27 (2%) | 44 |
| 0 | 233 (14%) | 168 (12%) | 401 |
| Number of previous pregnancies | | | |
| 1–3 | 875 (53%) | 758 (56%) | 1633 |
| ≥4 | 448 (27%) | 377 (28%) | 825 |
| Did mother receive antenatal care? | | | |
| No | 338 (21%) | 275 (20%) | 613 |
| Yes | 1309 (79%) | 1080 (80%) | 2389 |
| Self-reported previous HIV testing | | | |
| No | 646 (39%) | 354 (26%) | 1000 |
| Yes | 1001 (61%) | 1001 (74%) | 2002 |

*In this group there was one participant with unknown age.

***Table 1*: Baseline characteristics**

| | Participants | HIV tested | p value |
|---|---|---|---|
| Confirmed HIV test | | | <0·0001 |
| Control | 1355 | 740 (55%) | .. |
| Intervention | 1647 | 1514 (92%) | .. |
| Age group (years) | | | 0·753 |
| <24·9 | 665 | 492 (74%) | .. |
| 25–34·9 | 1793 | 1350 (75%) | .. |
| ≥35 | 518 | 392 (76%) | .. |
| Marital status | | | 0·615 |
| Divorced | 2 | 2 (100%) | .. |
| Married | 2809 | 2114 (75%) | .. |
| Separated | 15 | 10 (67%) | .. |
| Single | 176 | 128 (73%) | .. |
| Education level | | | 0·448 |
| None or primary | 778 | 576 (74%) | .. |
| Secondary | 1691 | 1272 (75%) | .. |
| Tertiary | 512 | 395 (77%) | .. |
| Employment | | | 0·017 |
| Full-time | 1079 | 827 (77%) | .. |
| Part-time | 671 | 522 (78%) | .. |
| Unemployed | 1199 | 870 (73%) | .. |
| Number of people in family | | | 0·736 |
| ≤2 | 484 | 359 (74%) | .. |
| 3–6 | 2070 | 1560 (75%) | .. |
| ≥7 | 399 | 305 (76%) | .. |
| Distance to health facility | | | 0·277 |
| 0–5 km | 1015 | 758 (75%) | .. |
| 5–10 km | 1149 | 854 (74%) | .. |
| 10–15 km | 506 | 394 (78%) | .. |
| >15 km | 293 | 229 (78%) | .. |
| Residency area | | | 0·260 |
| Rural | 2156 | 1635 (76%) | .. |
| Urban | 822 | 607 (74%) | .. |
| Age at first pregnancy (years) | | | 0·013 |
| <24·9 | 1849 | 1370 (74%) | .. |
| 25–34·9 | 963 | 752 (78%) | .. |
| ≥35 | 44 | 28 (64%) | .. |
| Number of previous pregnancies | | | 0·009 |
| 0 | 401 | 326 (81%) | .. |
| 1–3 | 1660 | 1229 (74%) | .. |
| ≥4 | 798 | 607 (76%) | .. |
| Self-reported previous HIV testing | | | 0·051 |
| No | 1000 | 729 (73%) | .. |
| Yes | 2002 | 1525 (76%) | .. |

***Table 2*: Predictors of HIV testing in pregnant women**

likely to access care and receive ART during pregnancy (2·8, 1·02–4·79; p=0·042). 61 (84%) of 73 women were accessing care at follow-up with no significant difference between groups (table 4).

## Discussion

Our study findings show that a culturally adapted, congregation-based approach delivered by trained volunteer health advisers can be used effectively to increase HIV testing in pregnant women. HIV counselling and testing is an important entry point for most forms of HIV prevention and control including PMTCT. Although barriers to HIV testing have been identified at the patient, provider, and health systems levels, barriers at the health systems level have been found to have the most adverse effect on HIV testing in pregnant women.[18,19]

Data from Nigeria suggest that in 2013, only 17·1% of women aged 15–49 years received an HIV test in the past 12 months and knew their result.[3] Absence of knowledge, low perception of personal risk, access, cost, stigma, and the fact that most women do not access prenatal care early in pregnancy are commonly identified barriers.[20–22] HBI was designed to overcome these barriers. Our finding is consistent with other studies showing that well developed community-based approaches that decentralise testing beyond health facilities and consistently made HIV tests available in environments that reduce these barriers[23–25] have led to increased HIV testing.[26–30]

We believe that several factors contributed to the magnitude of the effect seen in our study with regard to HIV testing. For example, prayer sessions were useful for early identification of pregnant women. These sessions provide multiple opportunities to offer HIV counselling and testing; the integrated and on-site approach to laboratory testing provided during church—organised baby showers were reported by participants as a substantial factor in the reduction of stigma associated with the HIV-only testing approach; involvement of male partners (who presented the Mama Packs to their spouses) removed the preconception of a women-only intervention and presented the baby showers as a family-oriented programme. Male involvement has been shown to be a crucial factor in pregnant women's acceptance of HIV testing.[31]

The strength of our study includes the fact that it took into consideration several factors that might affect HIV testing in Nigeria. Considering the role of faith for Nigerians, we collaborated with faith-based organisations that have well established social networks and are already involved in efforts to address HIV/AIDS in the study communities.[32] Most communities in Nigeria have at least one worship centre even when there are no accessible health facilities. Studies show that church-based clinics and hospitals play a significant part in prenatal care and deliveries for pregnant women, and that priests rank highly among people to whom a pregnant woman is most likely to disclose her HIV status.[7] We identified and used evidence-based elements of a successful programme in communities where faith has a prominent role.[33,34]

Churches were used as venues to identify pregnant women, implement the intervention, and for post-delivery follow-up, and thus served as the study venue. This approach is similar to the use of national chain pharmacies for influenza immunisation in the USA.[35] These neighbourhood stores are used because they are easily accessible, widely distributed, and as highly patronised as worship centres in most resource-limited settings. HBI is being adapted for implementation in mosques in northern Nigeria and Hindu temples in India. We expect to see a similar result in India and Nigeria because these venues serve a similar function as the churches or neighbourhood stores in the USA. Although community-based testing has been successfully used for HIV testing in our study environment, it was associated with substantial loss to follow-up as individuals with positive test results could not be identified owing to absence of identifying information such as social security numbers or government-issued identification with addresses.

| | Adjusted OR* (95% CI) | p value |
|---|---|---|
| Control *vs* intervention | 11·180 (8·77–14·25) | <0·0001 |
| Age group: ≥35 years *vs* <24·9 years | 1·129 (0·76–1·68) | 0·552 |
| Age group: 25–34·9 years *vs* <24·9 years | 1·008 (0·76–1·34) | 0·958 |
| Education level: secondary *vs* none | 0·982 (0·76–1·26) | 0·888 |
| Education level: tertiary *vs* none | 0·870 (0·608–1·25) | 0·445 |
| Working: part-time *vs* full-time | 0·964 (0·73–1·27) | 0·795 |
| Working: unemployed *vs* full-time | 1·264 (1·01–1·59) | 0·045 |
| Distance to health-care facility: 5–10 km *vs* 0–5 km | 1·159 (0·76–1·40) | 0·212 |
| Distance to health-care facility: 10–15 km *vs* 0–5 km | 1·159 (0·92–1·46) | 0·835 |
| Distance to health-care facility: ≥15 km *vs* 0–5 km | 1·033 (0·76–1·40) | 0·895 |
| Household size: 4–6 *vs* ≤3 | 0·801 (0·58–1·11) | 0·177 |
| Household size: ≥7 *vs* ≤3 | 0·731 (0·47–1·13) | 0·158 |
| Living area: urban *vs* rural | 0·833 (0·66–1·06) | 0·138 |
| Age of first pregnancy group: ≥35 years *vs* <24·9 years | 1·040 (0·44–2·49) | 0·929 |
| Age of first pregnancy group: 25–34·9 years *vs* <24·9 years | 0·748 (0·58–0·97) | 0·025 |
| Number of previous births: 1–3 *vs* 0 | 1·657 (1·16–2·37) | 0·006 |
| Number of previous births: ≥4 *vs* 0 | 1·443 (0·93–2·23) | 0·099 |
| Self-reported previous HIV testing: yes *vs* no | 1·711 (1·36–2·16) | <0·0001 |

*Adjusted ORs were based on multilevel analysis generalised linear mixed models with covariates of demographics, previous birth, and previous HIV testing.

***Table 3:*** **Adjusted odds ratio (OR) for no HIV testing in pregnant women**

| | Intervention group (n=41) | Control group (n=32) | Adjusted odds ratio (95% CI) | Total (n=73) |
|---|---|---|---|---|
| Linked to care before delivery | 34 (83%) | 14 (44%) | 6·2 (2·14–18·25) | 48 (48%) |
| Antiretroviral therapy during pregnancy | 24 (65%) | 12 (40%) | 2·8 (1·02–4·79) | 36 (54%) |
| Currently accessing care | 33 (81%) | 28 (88%) | 0·39 (0·04–3·99) | 61 (84%) |

***Table 4:*** **Linkage to care outcomes in HIV-positive women**

A full cost-effectiveness analysis was embedded within the trial and results will be reported separately. However, researchers and front-line public health professionals should consider several factors when trying to replicate or implement HBI to scale in other settings. These individuals should consider the costs associated with the Mama Packs given to the pregnant women as well as the cost of integrated laboratory tests. Nevertheless, these costs are within the range reported by programmes that showed the effectiveness of conditional and unconditional cash transfers in HIV prevention (de Walque, World Bank, unpublished data).[36] Also, the testing algorithm comprised routine tests offered to pregnant women during prenatal care. The decision to include a partial intervention (baby showers in control group churches) might have led to a higher HIV screening rate than would otherwise be expected for those communities. We chose this approach because ethical concerns related to study designs (eg, when control churches do not receive any intervention) are known to be barriers against effective implementation of congregation-based health programmes. The sample size and number of study sites were based on infant baptism records, but our intervention might have affected people outside of the study centre, especially in the intervention group where on-site integrated testing was offered.

Recruitment to the trial ended in 2013, but the communities elected to continue the programme owing to its popularity in pregnant women, lay health advisers, and priests. Each of the participating sites were provided with Mama Packs and cost of testing for sickle-cell disease is being defrayed by Healthy Sunrise Foundation, a non-profit organisation. HIV testing is provided free through our local PEPFAR-supported partner PeTR-GS. We are collecting data on HBI activities from the 40 churches that participated in the initial trial to assess sustainability. The US Agency for International Development (USAID) and UNICEF have visited various communities where HBI is active and are in discussion with the Nigerian National AIDS Control Agency to disseminate the programme to the states with the highest HIV prevalence in the country.

#### Contributors

EEE, MCO, COE, WY, and GO contributed to the study design and trial protocol. Patient recruitment and acquisition of data was done by EEE, MCO, AO, AGO, AEH, DP, and JET. All authors contributed to the organisation, conduct of study, data analysis, and interpretation of study data. EEE and JEE prepared the draft manuscript and all authors subsequently reviewed the output and made revisions.

#### Declaration of interests

We declare no competing interests.

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For the **ClinicalTrials.gov website** see https://clinicaltrials.gov/ct2/show/NCT01795261

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