BMJ Global Health

The impact of universal home visits with pregnant women and their spouses on maternal outcomes: a cluster randomised controlled trial in Bauchi State, Nigeria

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To cite: Cockcroft A, Omer K, Gidado Y, *et al*. The impact of universal home visits with pregnant women and their spouses on maternal outcomes: a cluster randomised controlled trial in Bauchi State, Nigeria. *BMJ Glob Health* 2019;**4**:e001172. doi:10.1136/bmjgh-2018-001172

Handling editor Seye Abimbola

Received 16 September 2018
Revised 10 December 2018
Accepted 4 January 2019

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ABSTRACT

Introduction Maternal mortality in Nigeria is extremely high. Access to quality antenatal and obstetric care is limited. In Bauchi State, we found maternal morbidity was associated with domestic violence, heavy work in pregnancy, ignorance of danger signs, and lack of spousal communication. This cluster randomized controlled trial tested the impact of universal home visits that discussed these upstream risk factors with pregnant women and their spouses, to precipitate household actions protecting pregnant women.

Methods We randomly allocated four wards in Toro Local Government Authority to immediate or delayed intervention. Female and male home visitors visited all pregnant women and their spouses in the two intervention wards every 2 months. We compared completed pregnancies between intervention and pre-intervention wards after 1 year. Primary outcomes were pregnancy, delivery, and postnatal complications, analysed with intention to treat using a cluster t-test. Ancillary analysis examined the influence of baseline and health service use differences.

Results Among 1837 women in intervention wards and 1853 women in pre-intervention wards, the intervention reduced problems in pregnancy and post partum: raised blood pressure (relative risk reduction (RRR) 0.120, cluster-adjusted 95% CI (Clca) 0.045 to 0.194; risk difference (RD) 0.116, 95% Clca 0.042 to 0.190) and swelling of face or hands (RRR 0.271, 95% Clca 0.201 to 0.340; RD 0.264, 95% Clca 0.194 to 0.333) and postpartum sepsis (RRR 0.399, 95% Clca 0.220 to 0.577; RD 0.324, 95% Clca 0.155 to 0.493). The intervention reduced the targeted upstream risk factors such as heavy work during pregnancy (RRR 0.234, 95% Clca 0.085 to 0.383; RD 0.222, 95% Clca 0.073 to 0.370). It did not increase use of antenatal care, institutional delivery or skilled birth attendance.

Conclusion Home visits reduced upstream maternal risks, improving maternal outcomes without increased use of health services. This could have implications in other settings with poor access to quality antenatal and delivery care services.

Key Questions

What is already known?

- Systematic reviews show home visits can reduce maternal morbidity and perhaps maternal mortality in low-income and middle-income countries; the impact is greater when coverage is higher.
- The mechanism for the impact of home visits is unclear; in some studies, home visits increased institutional deliveries, but they did not increase skilled birth attendance.

What are the new findings?

- The home visits were universal, with no pregnant women left out; the visitors shared recent local evidence about 'upstream' factors associated with maternal morbidity, encouraging household discussions, rather than encouraging women to attend routine antenatal care and to deliver in facilities.
- The home visits improved upstream risk factors and reduced complications of pregnancy and postnatal sepsis, without significantly increasing the load on facility-based antenatal or delivery care.

What do the new findings imply?

- Universal home visits that share evidence and provoke discussion between pregnant women and their husbands change upstream risk factors.
- Such home visits can reduce maternal morbidity without increased load on facilities for antenatal and delivery care, so could be relevant in places with high maternal mortality and poor maternal care services.

Trial registration ISRCTN82954580.

BACKGROUND

Maternal mortality is an urgent problem in Nigeria, which has a reported maternal

mortality ratio (MMR) of 814, among the highest in the world.[1] The situation is likely to be worse in the north of the country: a study in Bauchi State referral hospital reported 621 deaths in 12 067 un-booked deliveries (5.1%).[2] Much of the current discussion about maternal mortality hinges on attendance at facility-based antenatal care and deliveries.[3] But an analysis based on the 2013 Nigeria Demographic and Health Survey[4] reported that only 11% of women attending routine antenatal care (ANC) received a minimum acceptable quality of care and only 5% the desirable quality of care, and these figures were worse in the north.[5] Quality of care was based on 10 reported components of service at ANC visits.

Focus groups identified costly, poor-quality and inaccessible services, and uncooperative partners as reasons why women did not attend ANC.[6] Encouraging women to attend underfunded and low-quality services will not improve the already strained quality of care and may even compromise it further. This suggests a need to look *upstream* for ways to improve maternal health by influencing the conditions that produce risk factors for poor maternal outcomes.

There is evidence that home visits to pregnant women can improve outcomes for both mothers and their babies in developing countries. A 2010 systematic review of trials of home visits concluded they could reduce neonatal mortality, but did not consider impact on maternal outcomes.[7] A recent systematic review of trials of community-based interventions in developing countries, many including home visits, showed a reduction in maternal morbidity and possibly in maternal mortality,[8] while a meta-analysis of trials of birth preparedness and complication readiness interventions, some including home visits, showed a reduction in maternal mortality with adequate coverage of the intervention.9 In both of the recent reviews, only some of the intervention packages included home visits. Few of the studies took place in Africa, with only one in West Africa.[10] A 2016 systematic review of intervention studies to improve healthcare seeking for maternal and newborn illness in low-income and middle-income countries, mostly home visits and community mobilisation, reported no significant impact on seeking care for maternal illness or on maternal mortality.[11]

Maternal mortality and lack of ANC are related to the same structural factors in many developing countries: extreme poverty, powerful gender disparities, social marginalisation and low levels of education.[12] A cluster intervention addresses many of these contextual variables shared by neighbours. Knocking on the door of the home of every pregnant woman to discuss pregnancy risks with her and her spouse can be a structural intervention. It reduces the isolation of individual women and provides a strong message about the value of every pregnant woman. If *all* households are included, the intervention should reach those who do not attend ANC yet may be at high risk of adverse outcomes.

A 2009 study in Bauchi and Cross River states of Nigeria identified four associations with maternal outcomes: experience of domestic violence in pregnancy, heavy work during pregnancy, lack of basic knowledge of danger signs, and lack of communication with the spouse about pregnancy and delivery.[13] A pilot study in Giade Local Government Authority in Bauchi State established the feasibility and acceptability of universal home visits to pregnant women, including discussion of these four associations, and suggested an impact of the visits on maternal morbidity and mortality.[14] We are now undertaking a randomised controlled trial, in a stepped-wedge design,[15] to assess, at individual and cluster level, the acceptability and impact on maternal outcomes of universal home visits to engage pregnant women and their spouses, with and without additional video edutainment.[14] We report here the parallel group pragmatic cluster randomised controlled trial that is the first phase of the overall stepped-wedge trial.[14] The overall trial includes three waves, of two wards each, allocated to receive home visits immediately, after 1 year, and after a further year. After all wards in the trial have received home visits, we will examine the added value of the video edutainment provided in one of the wards in each wave.[14]

METHODS

The trial reported here compares maternal outcomes between two wards randomly allocated to receive home visits immediately and two wards allocated to receive home visits after a delay of 1 year. We have described the overall trial methods in detail elsewhere.[14]

The study took place in Toro Local Government Authority in Nigeria's north-eastern Bauchi State. The state has around 5 million residents, the main religion is Islam, family sizes are large and polygamy is common. Some 73% of women in Bauchi have no education, compared with 38% nationally.[4] Toro is the largest Local Government Authority, with a 2014 population of 437 000. More than 95% of the population is Muslim and predominantly Hausa (80%) or Fulani (12%) ethnicity. A 2013 survey found 22% of women in Bauchi and 27% in Toro had a skilled attendant for their last delivery, and 57% in Bauchi and 71% in Toro had to pay in cash or kind when attending ANC in a government facility.[16] Also, 82% of women in Bauchi and 60% in Toro did not reduce heavy work before the last trimester of pregnancy, and 17% in Bauchi and 16% in Toro experienced domestic violence during their last pregnancy.[16]

Participants and intervention

All women of childbearing age (14–49 years) in all households in the intervention wards were eligible for the study. Each ward included urban, rural and rural remote communities. Among these women, all those who became pregnant during the study period were visited at home several times during their pregnancies; their husbands were also visited during the pregnancies.

The protocol provides a full description of the intervention.[14] Each home visit team of one woman and one man covered around 300 households and visited every household every 2 months. The female home visitors typically visited the households and followed the pregnant women during daylight hours, while the male home visitors typically visited the same households and spoke to the spouses of the pregnant women in the evenings or at weekends, when the men were at home. We recruited the home visitors mostly from the intervention communities, and trained and evaluated them before they began the work. On the first visit, the female visitor asked about household demographics and socioeconomic status. On each subsequent visit, she checked how many women of childbearing age were in the household, noted how many were pregnant, and followed those registered as pregnant with a surveillance questionnaire and discussion about the four issues related to pregnancy risk in a previous study in the state: heavy work in pregnancy, experience of domestic violence, lack of communication with the spouse and lack of knowledge about pregnancy danger signs.[13] Male visitors separately interviewed and held discussions with the partners of the pregnant women, also every 2 months. The intention was to provoke household discussion and action on the risk factors. A visit after delivery recorded information about the whole pregnancy and delivery.

The home visitors entered interview responses directly into GPS-enabled android handsets preloaded with information for the home visitors to share with pregnant women and their spouses, along with instructions for referring pregnant women who reported danger signs to a local clinic. They uploaded records to a central server after each visit. We used open-source Open Data Kit software for the electronic data collection.[17] The GPS locations included in the uploaded records allowed us to check that the home visitors actually conducted interviews in the intended households.

The home visitors did not routinely encourage pregnant women to attend for routine ANC or to deliver in health facilities. However, recognising that some visited women might report danger signs during their pregnancies, home visitors' training included this eventuality and their handsets carried a decision aid of what to do in different cases, including when to refer to a health facility. The training stressed the importance of conducting all interviews with privacy and covered practical ways of ensuring privacy in the household setting in Bauchi. It also covered how to handle any distress caused by discussion of sensitive topics, such as domestic violence.

The study conformed to the principles embodied in the Declaration of Helsinki. The research team discussed the home visits with the leadership of all communities in the participating wards to get their approval to proceed. We treated all responses from participants as confidential, with no names or identifying information recorded.

Outcomes

The primary outcome was maternal morbidity during pregnancy and within 6 weeks after delivery, as reported by women after completed pregnancies. The questionnaire asked about pregnancy complications including severe headaches, swelling of hands and feet, dizziness or blurred vision, high blood pressure (if measured during the pregnancy), convulsions and vaginal bleeding during pregnancy. It also enquired about perineal trauma (cut or tear) during delivery and delivery by Caesarean section. Postpartum complications included wound opening, high fever and smelly discharge. We defined postpartum sepsis as the presence of any one of these three complications.

Behavioural and knowledge indicators specifically targeted by the visits were heavy work during pregnancy, experience of verbal and physical domestic violence, communication with the spouse about pregnancy and delivery, and knowledge of danger signs during pregnancy and delivery. Indicators of access to healthcare were at least one ANC visit to a facility, at least one blood pressure measurement, urine tested at least once, delivery attended by a trained health worker (community health worker, nurse, midwife or doctor), delivery in a health facility, and a postnatal visit within 6 weeks.

In the intervention wards, the home visitors followed pregnant women with bimonthly visits and administered an electronic questionnaire after delivery; we included in the present analysis all post-delivery questionnaires completed up to 31 December 2017. In the pre-intervention wards, the home visitors administered the same questionnaire to women in the baseline visit, asking about completed pregnancies in the last 12 months.

Sample size

Our sample size calculations used the clinical trials simulator of Taylor and Bosch.[18] Our 2013 study in the same local government authority[16] found 60% of women did not reduce heavy work in pregnancy and 58% reported postpartum infection or another serious complication of pregnancy. At this frequency, with an estimated 2880 births in each ward over a 2-year period, our study could detect a 20% reduction in complications (80% power at the 5% level, k=0.05) between two intervention wards and the two pre-intervention wards.

The study was not powered to show an impact on maternal mortality, although this should be measurable with later roll-out to other local government authorities. The Toro MMR (around 800 per 100 000 live births) implies around 35 maternal deaths in each ward over 2 years. The wards with home visits would have to reduce mortality by 35% to be detected with 80% power at the 5% level (k=0.06).

Randomisation and masking

At the beginning of the study, random allocation of six participating wards in Toro Local Government Authority generated three groups of two wards each.

An epidemiologist not involved in the fieldwork (NA) generated the allocation sequence. We first divided the six wards into two sets, geographically apart. For each group of two wards, we randomly selected one ward from each of these two sets. We report here the comparison of outcomes at 1 year between the first group of two wards (intervention wards) and the second group of two wards (pre-intervention wards). The third group of two wards will receive visits after a further year's delay.

There was no possibility to conceal allocation once the intervention began. The home visitors conducting interviews for measuring outcomes could not be blinded to group assignment but, hired simply to visit households and interview participants, they did not have any reason to interview differently in intervention and control sites.

Statistical methods

Ward was the unit of randomisation, intervention and analysis. We used the Mantel-Haenszel procedure[19] adjusted for clustering (Lamothe method)[20] to examine differences between the intervention and pre-intervention wards at baseline. This first assessment of the impact of home visits contrasted primary outcomes after 1 year between the intervention and pre-intervention wards.

The principal analysis of the primary outcomes used a t-test in an intention-to-treat analysis of cluster-specific rates.[21] With cluster as unit of analysis, we estimated relative risk reduction (RRR) as one minus the relative risk (RR), using variance of the RR (Delta method) to estimate CIs. We estimated the number needed to treat (NNT) as the reciprocal of risk difference (RD), and intra-cluster correlation (ICC) by dividing the between-cluster variance by the between-cluster and within-cluster variance across the control series.[22]

Prespecified ancillary analyses used generalised estimating equations for logistic regression (exchangeable matrix, 1000 iterations), assuming an exchangeable correlation structure within wards, to incorporate the cluster design, any differences at baseline, and any differences in use of health services during the pregnancy and delivery.[23] This analysis examined the possibility that these differences between intervention and pre-intervention wards explained the findings. We wanted to be sure any impact of home visits was not simply due to baseline differences, or to increased use of health services during pregnancy and delivery.

A supplementary analysis examined associations between reports of pregnancy complications and attendance at ANC and delivery in health facilities.

RESULTS

Figure 1 shows the flow of clusters and individual participants through the trial. Implementation followed the protocol. Recruitment of participants for home visits within the first two wards began in March 2016. Recruitment of participants for home visits in the second two wards began about 1 year later. We compared maternal

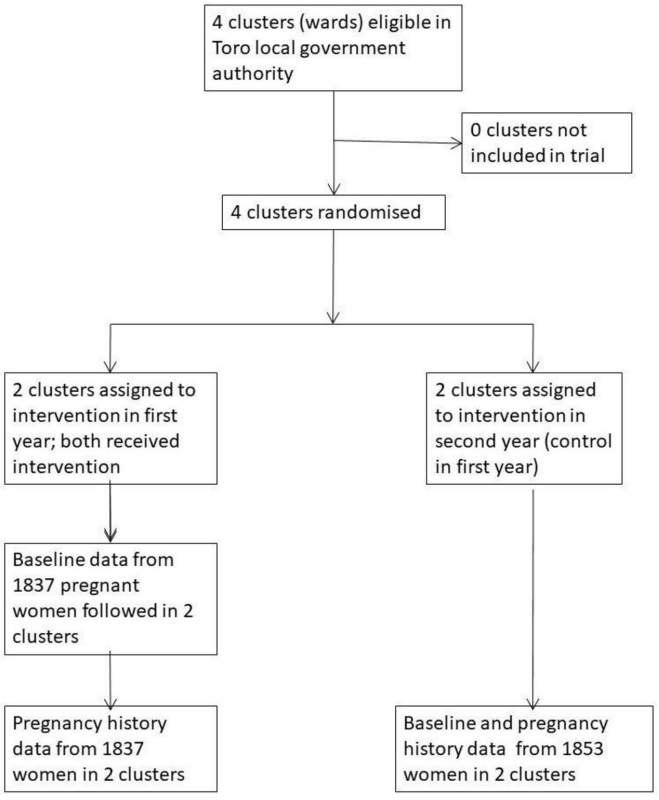

Figure 1 Participant flow in the trial.

pregnancy and delivery outcomes between the intervention and pre-intervention wards using data on completed pregnancies accrued in the intervention wards during approximately 1 year of intervention, and collected from the pre-intervention wards in their baseline visit before starting the intervention there.

We report here the analysis of data from 3690 women reporting on completed pregnancies: 1837 women in households in the intervention wards and 1853 women in households in the pre-intervention wards. There were 2271 women expected to complete pregnancies in the pre-intervention wards by 31 December 2017; 1837 (81%) of them completed a post-delivery questionnaire. This is an underestimate of the follow-up rate because some of the remaining women completed the post-delivery questionnaire after the 31 December cut-off.

Table 1 shows baseline characteristics of women in the intervention and pre-intervention wards. The proportion of women from non-remote communities was higher in the intervention wards than in the pre-intervention wards. Compared with women in the pre-intervention wards, women in the intervention wards were more likely to be from a household with an educated head and more likely to have some formal education themselves. The proportion of women in the low-risk age group for pregnancy (18–35 years) was lower in intervention wards; a higher proportion were adolescents (age 14–19 years), while the proportions over 35 years old or over 39 years old did not differ between intervention and control wards. A higher proportion of women in the intervention wards had less

Table 1 Characteristics of the women reporting on pregnancies in the intervention and pre-intervention (control) wards

Characteristic	% (n) Intervention wards	Pre-intervention wards	OR (95% CIca)
No of women	1837	1853	
From non-remote community	78.4 (1441/1837)	56.7 (1051/1853)	**2.78 (1.64 to 4.71)**
From male-headed household	99.6 (1585/1591)	99.7 (1794/1800)	0.88 (0.23 to 3.33)
From household where head has some formal education	54.7 (848/1551)	40.9 (729/1783)	**1.74 (1.36 to 2.24)**
In low-risk age group (18–35 years)	86.8 (1594/1837)	90.4 (1675/1853)	**0.70 (0.62 to 0.78)**
Adolescent (age <20 years)	15.7 (289/1837)	10.4 (192/1853)	**1.62 (1.24 to 2.10)**
Age more than 35 years	6.5 (119/1837)	6.6 (122/1853)	0.98 (0.83 to 1.17)
Age more than 39 years	5.0 (91/1837)	5.0 (91/1853)	1.00 (0.92 to 1.08)
Less than five previous pregnancies	74.6 (1371/1837)	63.5 (1176/1853)	**1.69 (1.34 to 2.14)**
With any formal education	42.9 (788/1835)	35.1 (650/1850)	**1.39 (1.27 to 1.53)**
With enough food in the last week	95.2 (1748/1836)	95.1 (1762/1853)	1.03 (0.61 to 1.73)

Bold font indicates a difference significant at the 5% level.
The relatively high level of missing data for information about the household head in intervention wards arose because some workers mistakenly recorded initial visits as "follow-up" rather than "baseline" and did not collect the information about the household head.
95% CIca=cluster-adjusted 95% CI; OR=Mantel-Haenszel OR.

than five previous pregnancies. We use food insufficiency in the last 1 week as an indicator of severe poverty and this did not differ between intervention and control wards.

Outcomes and estimation of impact

Table 2 shows reported pregnancy, delivery and postnatal complications, compared between intervention and pre-intervention wards on an intention-to-treat basis using the cluster t-test. Except for convulsions during pregnancy, which affected less than 1% in the intervention group and 5% in the control group, all the reported pregnancy complications we measured were significantly less common in the intervention wards. The proportions of women reporting perineal trauma or Caesarean section, or other problems during delivery, were not significantly different between intervention and pre-intervention wards. Women in the intervention wards were significantly less likely to report fever or smelly discharge within 6 weeks. The reduction in rate of postpartum sepsis (any one of the three elements of wound opening, fever or smelly discharge) was 32.4%, corresponding to a NNT of 3.

There were statistically significant improvements in the risk behaviours and knowledge targeted by the home visits in the intervention wards (table 3). Compared with women in the pre-intervention wards, women in the intervention wards reported less heavy work in pregnancy and less physical domestic violence in pregnancy; they reported more communication with partners about pregnancy and delivery, and they had better knowledge of danger signs during pregnancy and delivery.

Table 4 shows the use of health services during pregnancy, delivery and post partum in women in the intervention and pre-intervention wards. For most of the measured variables, the proportion of women who used services was slightly higher in the intervention wards, but none of the differences was significant at the 5% level.

As shown in the tables in online supplementary file 1, baseline differences or differences in use of health services did not explain the impact detected on the outcomes in tables 2 and 3. In some cases, including baseline variables and use of services in the model increased the strength of association between the intervention and the outcome (online supplementary file 1).

The supplementary analysis of associations between reports of pregnancy complications and use of health services found that, for most pregnancy complications, women with the complication were somewhat more likely to attend ANC and to deliver in a health facility, after stratifying by intervention status (online supplementary file 2). These associations were significant at the 5% level only for

Table 2 Pregnancy, delivery and postnatal complications reported by 1837 women in intervention wards and 1853 women in pre-intervention (control) wards

Outcome	Proportion (n)		RRR (95% CIca)	RD (95% CIca)	NNT	ICC
	Intervention wards	Pre-intervention wards				
Pregnancy complications						
No persistent headache	0.950 (1746/1837)	0.421 (780/1853)	**0.557 (0.434 to 0.680)**	**0.530 (0.403 to 0.656)**	2	0.027
No swelling of face or hands	0.974 (1790/1837)	0.711 (1317/1853)	**0.271 (0.201 to 0.340)**	**0.264 (0.194 to 0.333)**	4	0.010
No convulsions	0.992 (1823/1837)	0.951 (1763/1853)	0.041 (–0.006 to 0.089)	0.041 (–0.007 to 0.088)		0.020
No vaginal bleeding	0.978 (1797/1837)	0.903 (1674/1853)	**0.076 (0.034 to 0.119)**	**0.075 (0.032 to 0.117)**	14	0.007
No dizziness or blurred vision	0.969 (1780/1837)	0.569 (1055/1853)	**0.412 (0.349 to 0.476)**	**0.400 (0.264 to 0.535)**	3	0.007
No raised blood pressure*	0.966 (1409/1458)	0.851 (1269/1492)	**0.120 (0.045 to 0.194)**	**0.116 (0.042 to 0.190)**	9	0.016
No 'other problem' in pregnancy	0.961 (1766/1837)	0.861 (1597/1853)	**0.104 (0.043 to 0.164)**	**0.100 (0.040 to 0.159)**	10	0.010
Delivery and postnatal complications						
No perineal tear, cut or Caesarean section	0.931 (1710/1837)	0.955 (1769/1853)	–0.026 (–0.134 to 0.082)	–0.024 (–0.123 to 0.075)		0.042
No 'other problem' in delivery	0.977 (1795/1837)	0.963 (1785/1853)	0.014 (–0.007 to 0.035)	0.014 (–0.007 to 0.035)		0.003
No wound opening or infection after delivery	0.994 (1808/1818)	0.985 (1816/1844)	0.010 (–0.007 to 0.026)	0.010 (–0.007 to 0.026)		0.005
No fever within 6 weeks of delivery	0.833 (1531/1837)	0.532 (986/1853)	**0.362 (0.195 to 0.528)**	**0.301 (0.143 to 0.460)**	3	0.031
No smelly discharge within 6 weeks of delivery	0.950 (1746/1837)	0.828 (1534/1853)	**0.129 (0.046 to 0.212)**	**0.123 (0.041 to 0.205)**	8	0.017
No sepsis within 6 weeks of delivery	0.811 (1478/1822)	0.488 (903/1852)	**0.399 (0.220 to 0.577)**	**0.324 (0.155 to 0.493)**	3	0.033

Bold font indicates the contrast is significant at the 5% level.
*Among those women who had their blood pressure measured
95% CIca, cluster-adjusted 95% CI; ICC, intracluster correlation; NNT, number needed to treat (1/RD); RD, risk difference; RRR, relative risk reduction (1–RR (relative risk)).

persistent headache and dizziness or blurred vision and ANC attendance. The strength of associations between complications and use of health facilities was not significantly different between intervention and control wards.

Since there was less than 1% missing data for the main outcomes of complications in pregnancy and delivery and targeted risk factors and for baseline characteristics (except for information about the household head) in both the intervention and pre-intervention wards, we did not conduct multiple imputation to examine the possible effect of missing data. We did not include characteristics of the household head in any of the adjusted analyses shown in online supplementary file 1.

Visited women reporting danger signs in pregnancy

In 1100 of the 12 359 visits to pregnant women (most women were visited several times) in the intervention wards, the visited woman reported one or more danger signs. The most frequent report was of persistent severe headaches, reported in 621 (56.5%) of cases, and dizziness (352, 32%). The female workers gave referral slips for a nearby clinic to the woman in 977 (89%) of these cases. They followed up 347 of these referrals on subsequent visits; 212 (61%) had visited the clinic as advised.

DISCUSSION

The Toro trial sought to assess the impact of universal home visits on maternal outcomes. We found a clear advantage in the intervention wards. Universal home visits to pregnant women and their husbands reduced nearly all the reported complications in pregnancy that we examined and reduced reported postpartum sepsis. They also reduced reported domestic violence during

Table 3 Targeted risk factors among 1837 women in intervention wards and 1853 women in pre-intervention (control) wards

Outcome	Proportion (n)		RRR (95% CIca)	RD (95% CIca)	NNT	ICC
	Intervention wards	Pre-intervention wards				
Reduced heavy work during pregnancy	0.948 (1734/1830)	0.726 (12684/1747)	**0.234 (0.085 to 0.383)**	**0.222 (0.073 to 0.370)**	5	0.043
Reduced heavy work before third trimester	0.712 (1288/1810)	0.250 (425/1698)	**0.648 (0.496 to 0.801)**	**0.461 (0.310 to 0.613)**	3	0.027
No physical domestic violence during pregnancy	0.974 (1772/1820)	0.909 (1677/1844)	**0.066 (0.046 to 0.086)**	**0.064 (0.045 to 0.084)**	16	0.001
Discussed pregnancy with spouse	0.899 (1643/1827)	0.695 (1266/1821)	**0.227 (0.061 to 0.393)**	**0.204 (0.044 to 0.365)**	5	0.041
Knows any danger sign in pregnancy	0.984 (1808/1837)	0.838 (1552/1853)	**0.149 (0.101 to 0.197)**	**0.147 (0.098 to 0.195)**	7	0.007
Knows three or more danger signs in pregnancy	0.704 (1294/1837)	0.287 (531/1853)	**0.593 (0.485 to 0.702)**	**0.418 (0.315 to 0.521)**	3	0.011
Knows any danger sign in delivery	0.968 (1779/1837)	0.752 (1394/1853)	**0.223 (0.099 to 0.348)**	**0.216 (0.092 to 0.341)**	5	0.035
Knows three danger signs in delivery	0.243 (447/1837)	0.047 (87/1853)	**0.807 (0.708 to 0.906)**	**0.196 (0.144 to 0.249)**	6	0.005

Bold font indicates the contrast is significant at the 5% level.
95% CIca, cluster-adjusted 95% CI; ICC, intracluster correlation; NNT, number needed to treat (1/RD); RD, risk difference; RRR, relative risk reduction (1−RR (relative risk)).

pregnancy and improved the other targeted risk factors (heavy work in pregnancy, lack of spousal communication and lack of knowledge about danger signs). The improvement in outcomes was not due to increased use of health services. Use was slightly higher in intervention wards than in pre-intervention wards, but the difference was not significant at the 5% level, and the ancillary analysis indicated that the improvement in outcomes in the

Table 4 Use of health services during pregnancy and delivery among 1837 women in intervention wards and 1853 women in pre-intervention (control) wards

Outcome	Proportion (n)		RRR (95% CI)	RD (95% CI)	ICC
	Intervention wards	Pre-intervention wards			
Attended any ANC	0.887 (1597/1800)	0.824 (1526/1851)	0.071 (−0.046 to 0.187)	0.063 (−0.044 to 0.170)	0.022
four or more ANC visits	0.480 (832/1735)	0.424 (770/1817)	0.116 (−0.578 to 0.180)	0.056 (−0.299 to 0.410)	0.121
Blood pressure measured at least once	0.677 (1236/1827)	0.671 (1231/1835)	0.008 (−0.187 to 0.203)	0.006 (−0.127 to 0.138)	0.018
Urine tested at least once	0.695 (1270/1828)	0.634 (1174/1851)	0.087 (−0.298 to 0.472)	0.060 (−0.219 to 0.340)	0.084
Delivered in a health facility	0.301 (475/1579)	0.219 (391/1785)	0.272 (−0.162 to 0.705)	0.082 (−0.071 to 0.235)	0.028
Had any assistance at delivery	0.811 (1280/1579)	0.887 (1582/1783)	−0.095 (−0.238 to 0.049)	−0.077 (−0.186 to 0.033)	0.022
Delivered by a skilled health worker	0.293 (463/1579)	0.227 (404/1783)	0.227 (−0.213 to 0.668)	0.067 (−0.081 to 0.214)	0.026
Postnatal visit within 6 weeks	0.355 (645/1818)	0.254 (470/1850)	0.284 (−0.020 to 0.588)	0.101 (−0.027 to 0.228)	0.017

ANC, antenatal care; 95% CIca, cluster-adjusted 95% CI; ICC, intracluster correlation; NNT, number needed to treat (1/RD); RD, risk difference; RRR, relative risk reduction (1−RR (relative risk)).

intervention wards was not explained by the higher use of health services during pregnancy and delivery in these wards.

Our findings advance the available evidence about home visits to pregnant women, especially universal visits in contexts with high maternal mortality and limited access to services. A 2014 systematic review of community interventions dealing with birth preparedness and complication readiness included 14 randomised trials in developing countries, five including home visits.[9] The authors concluded that the interventions reduced maternal mortality when they covered more than 30% of the targeted women. Based on few studies, home visits seemed most effective when combined with community-based group sessions. Lassi and Bhutta reviewed 26 cluster-randomised or quasi-randomised trials of community interventions to improve maternal and newborn health, 19 of them from Asia and 17 of them including home visits.[8] They found an impact on complications of pregnancy and delivery, with a possible impact on maternal mortality.

The three recent systematic reviews of community-based interventions found no increase in skilled birth attendance associated with the interventions that included home visits[8 9 11]; two found an increase in institutional deliveries.[8 11] A 2015 trial in Tanzania reported home visits increased institutional deliveries,[24] and a systematic review of interventions to increase attendance at ANC concluded they did so without improving maternal mortality.[25] Our finding of no significant increase in use of antenatal and delivery services in the intervention wards suggests that reduction in the upstream risks led to the improved maternal outcomes we documented. The home visitors in our study referred women with danger signs to a local clinic (in about 8% of visits), but despite this the women in intervention wards did not report a significantly higher rate of ANC visits. Women with danger signs were somewhat more likely to attend ANC in both intervention and pre-intervention wards, but most associations were not statistically significant and were not stronger in intervention wards.

The stronger impact with higher coverage noted in the Soubeiga *et al* review[9] is not surprising because the same factors that increase maternal risk also limit their ability to attend health facilities for ANC[26] and probably to participate in women's groups. The women not reached by an intervention with partial coverage may well be the most at risk. The home visits intervention in our study deliberately set out to visit all pregnant women in a defined area, to ensure we reached the most marginalised women. Studies of institution-based ANC care are almost all confounded by the fact that attendance is not random but determined by the very factors that put pregnant women at risk[27]; our trial took antenatal education and discussion to every doorstep and provides evidence of impact including among those at most risk.

The content of the home visits in previous studies varied but often consisted of educating women and other family members about danger signs in pregnancy and delivery and, in some cases, encouraging them to deliver in health facilities. A key difference in our study was that the visits provoked discussion using recent local evidence about factors associated with maternal risk, actionable by the households themselves.[13] On each visit, the home visitors asked women and their spouses about these factors and what action the household was taking; they did not tell them what actions to take. The encouraging if not surprising consequence was that the intervention reduced these upstream risk factors. We used a similar approach of 'socialising evidence for participatory action' in a successful trial of community mobilisation for dengue prevention in Mexico and Nicaragua.[28 29]

Our findings are relevant to other parts of Bauchi and Nigeria, and probably also to other countries with high levels of maternal mortality and underfunded health services. Since the intervention did not address facilities or healthcare practices, any impact will be limited to upstream determinants. Universal home visits should result in more referrals of those who need the extra attention to survive, so they could increase the demand on services.

An important concern is ensuring sustainability of universal home visits, through policy and allocation of resources. Our project took a participatory approach to integrated knowledge translation, involving research users throughout the research process.[30] Government officials, healthcare providers and communities in Bauchi State contributed to the research design. As planned in the overall stepped-wedge trial, trained government officers have now taken over the management of the home visits in the first two wards.[14] We expect our trial, with its embedded training of government officers, will help to consolidate the lessons local stakeholders draw about their own system.

Strengths and limitations

Because the visits reached all pregnant women, and their spouses, at home, we could measure the impact on all women, including those who would not access institution-based interventions or even community groups. Self-reports of pregnancy and delivery complications could potentially be unreliable, but there is no reason to believe women in intervention wards, who were significantly more aware of danger signs, would under-report complications compared with women in pre-intervention wards. If anything, the measured impact is likely to be an underestimate. There were only two wards (clusters) each in the intervention and control groups, and it is possible that there was an imbalance of unmeasured cluster-level covariates between the groups. The possibility of serious imbalance is reduced by the fact that all the clusters were in one local government authority area, which is quite homogeneous in terms of religion, ethnicity and socioeconomic status.

CONCLUSION

The Toro trial is the first to confirm impact of universal home visits on maternal outcomes in West Africa. The home visits reduced upstream maternal risks, improving outcomes without increased use of health services. This service delivery strategy, reaching all pregnant women, could be relevant in places with high maternal mortality and poor maternal care services.

Acknowledgements We thank the home visitors and their supervisors for their conscientious work collecting data and supporting women and their spouses, and the women and men in the communities in this study who gave their time to respond to questionnaires.

Contributors AC contributed to design of the study, led implementation, contributed to the analysis and co-drafted the manuscript. KO and YG contributed to design of the study, led the implementation in Nigeria, and contributed to the analysis and drafting of the manuscript. AA designed the database, supported data management and reviewed the manuscript. MCB, UA, AIG and YY supported the implementation in Nigeria and reviewed the manuscript. NA conceived and designed the study, conducted the analysis and co-drafted the manuscript.

Funding This work was carried out with the aid of a grant from the Innovating for Maternal and Child Health in Africa initiative, a partnership of Global Affairs Canada (GAC), the Canadian Institutes of Health Research (CIHR) and Canada's International Development Research Centre (IDRC). The Quebec Population Health Research Network (QPHRN) and the International Development Research Centre (IDRC) contributed to the financing of this publication.

Competing interests None declared.

Patient consent for publication Obtained.

Ethics approval The Bauchi State Health Research Ethics Committee approved the trial on 12 May 2015 (NREC/12/05/2015/12), as did the McGill Faculty of Medicine IRB on 23 June 2015 (A06-B35-15A).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Anonymised participant data for the findings reported in this article will be available only after completion of the whole stepped-wedge trial and publication of the findings. Researchers wishing to have access to the data should submit a request to AC (anne.cockcroft@mcgill.ca).

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