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Effect of continuum-of-care intervention package on improving contacts and quality of maternal and newborn health care in Ghana: a cluster randomized controlled trial

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ABSTRACT

Objective: To evaluate the effect of a continuum-of-care intervention package on the quality of care during the contacts of women and newborns with health-care providers.

Design: A cluster randomized controlled trial.

Setting: 32 sub-districts in 3 rural sites in Ghana.

Participants: Women who delivered during the trial period were eligible for participating in the trial. The baseline survey involved 1,480 women who delivered before the intervention, and the follow-up survey involved 1,490 women who received maternal and newborn care during the trial.

Interventions: The intervention package included: training health-care providers, utilizing an educational and recording tool named "continuum-of-care card", providing the first postnatal care (PNC) by retaining women and newborns at health-care facility or home visit by health-care providers.

Outcome measures: Adequate contacts were defined as at least 4 contacts during pregnancy, delivery with assistance of skilled health-care providers at a health-care facility, and 3 timely contacts within 6 weeks postpartum. High-quality care was defined as receiving 6 care items for antenatal care (ANC), 3 for peripartum care (PPC), and 14 for PNC.

Results: The difference-in-difference (DiD) estimators of having adequate contacts with high-quality care were 2.7 (p=0.54) at ANC, 2.0 (p=0.73) at PPC, and 12.7 (p=0.14) at PNC in the intention-to-treat design. In the per-protocol design that assigned the study sample by possession of the continuum-of-care card, the DiD estimators were 3.2 (p=0.52) at ANC, 7.4 (p=0.27) at PPC, and 20.7 (p=0.01) at PNC. Residential site and national health insurance membership were associated with adequate contacts with high-quality care in the intervention group in the follow-up survey.

Conclusions: The interventions increased contacts with health-care providers and quality of care during PNC. However, a large gap remains between contacts and quality-adjusted contacts. Maternal and newborn care in Ghana needs to improve its continuity and quality.

Trial registration number: (90618993)

Strengths and Limitations

- This was a cluster randomized controlled trial conducted in three rural sites which had diverse ecological characteristics and operated the Health and Demographic Surveillance System.
- This study assessed the effect of intervention on the process dimension of quality-of-care in antenatal, peripartum, and postnatal care accordingly, although the measurements were not standardized.
- The study results could be affected by uneven cluster allocation and the implementation in intention-to-treat design.
- However, our analysis showed that regular contacts with health-care providers did not guarantee quality of care, which suggests that maternal and newborn care program needs to improve continuity and quality of care.

INTRODUCTION

Maternal and newborn health has significantly improved during the Millennium Development Goals era. Women and newborns still encounter a life-threatening risk from the third trimester to the first month postpartum in resource limited countries.[1,2] A key strategy to maintain maternal and neonatal health throughout the high risk period is to provide effective interventions continuously during the high-risk period,[3] namely Continuum of Care (CoC). However, CoC remains a critical challenge in many countries. In our previous study, for example, only 8% of women completed CoC from pregnancy to postpartum period.[4] Moreover, regular contacts with health-care providers alone would not improve maternal and newborn health outcomes if they did not receive quality care.[5]

Currently, maternal and newborn health research provides no comprehensive definition and measurements of quality of care.[6] In 1988, Donabedian suggested a framework for quality of care assessment.[7] In the framework, quality of care is assessed with 3 dimensions: structure, process, and outcomes.[7] Using this framework, existing literature measured quality of care by creating composite indexes of structure and/or process of care,[8-11] and identified remarkable gaps between contacts with health-care providers and actual quality of care during the contacts.[9,10,12,13] In addition, previous studies evaluated the effects of interventions on improving process of care (e.g., receiving iron tablets, tetanus toxoid injections, HIV testing, intermittent preventive treatment for malaria, or basic newborn care).[14-16] However, to our best knowledge, few intervention studies have evaluated the effects on both contacts with health-care providers and quality of care from pregnancy to the postpartum period.

Ghana is one of the sub-Saharan African countries with an estimated maternal mortality ratio of 380/100,000 live births in 2013.[17] Neonatal mortality rate was 29/1,000 live births in 2010-2014, with a minor decline in the last decade.[18] The government of Ghana introduced health policies to mitigate the financial and geographical constraints affecting the access to health-care services: community-based health planning and services (CHPS) initiative in 1999,[19]

and national health insurance scheme in 2004.[20] However, maternal and newborn health remains a high-priority challenge, and further effort is needed to strengthen the continuum of care and improve the quality of care under the implementation of these policies.

Ghana's Ensure Mothers and Babies Regular Access to Care (EMBRACE) implementation research aimed to strengthen CoC.[21] The major activities included the development and implementation of an intervention package and evaluation of its effect on CoC. Based on the findings of formative research,[4] we developed an intervention package to ensure CoC with health-care providers during ANC, peripartum care (PPC), and PNC. Although CoC is the primary outcome for the impact evaluation,[22] quality of care during the regular contacts is another important outcome for the process evaluation, which provides multifaceted implications for maternal and newborn health program. Therefore, this study aimed to examine the effect of an intervention package on both contacts with health-care providers and quality of care, to identify the gaps between adequate contacts and quality-adjusted adequate contacts, and to determine the factors associated with having adequate contacts with high-quality care among women in the intervention group.

METHODS

Study design and setting

This was a cluster randomized controlled trial using the effectiveness-implementation hybrid design registered in ISRCTN (90618993).[22] We targeted 3 rural sites in Ghana: Navrongo (northern), Kintampo (central), and Dodowa (southern). Ghana Health Service had Health Research Centers (HRCs) in the 3 sites, and these HRCs operated the Health and Demographic Surveillance System.

Each site covered 2 districts and consisted of 36 sub-districts. We included 32 sub-districts in this study (Navrongo, 12; Kintampo, 12; and Dodowa, 8) and excluded 4 sub-districts because of other projects implemented or planned during our intervention period. We

used sub-district as a cluster unit as it was the primary unit of the health system. In the pre-intervention facility assessment, the percentage of health-care facilities with at least one midwife was 47% in Navrongo, 36% in Dodowa, and 21% in Kintampo.

We created 16 pairs from the 32 clusters, taking into account the population, the volume of delivery, and the number of midwife per cluster. A data analyst who was not a member of the study team randomly allocated the paired clusters using computer-generated random sequences. However, we assigned 3 sub-districts with a district hospital to the intervention group as majority of the childbirths took place in the hospitals. We informed about the implementation of the intervention to the community people and health-care providers in the intervention group only. However, complete blinding was not feasible; we implemented the intervention in the intention-to-treat design, which did not control for women's choice and access to health-care facilities across a cluster boundary.

Participants and intervention

Women who were aged between 15 – 49 years old, and delivered between October 1, 2014 and September 30, 2015 in the intervention group were eligible for study enrolment.[22]

We implemented the intervention for 12 months (October 1, 2014 to September 30, 2015). The details of the intervention were described previously.[22] Women were enrolled to the intervention when they had contacts with health-care providers anytime from pregnancy to the postpartum period.

The intervention package was composed of 4 interventions. First, health-care providers underwent reorientation about CoC. Second, health-care providers distributed the CoC card to women, which contains the schedule and actual dates of contacts with health-care providers, information on essential care and birth preparedness, and the presence of danger signs. Health-care providers and women utilized the CoC card in every contact. Third, health-care providers retained women and their newborns in the health-care facility for the first 24 hours postpartum to provide the first postnatal care. Fourth, health-care providers made home visits to provide

postnatal care to women and their newborns within the first 48 hours if they missed the first postnatal contact by 24 hours postpartum.

We emphasized to implement the intervention using the existing health system and resource; all intervention facilities in the 3 sites had re-orientation of health-care providers, and implemented all or a part of the intervention package depending on availability of resource and infrastructure. In addition, district health management teams conducted monthly supervision in health-care facilities, monitored the performance of the interventions, and had a monthly meeting to report the progress and discuss the challenges in collaboration with research teams. In the control group, women and their newborns received the standard care.

Survey

We conducted the baseline survey from July to September 2014, with a sample of 1,500 women who delivered between September 1, 2012 and June 30, 2014, and the follow-up survey was performed from October to December 2015, with a sample of 1,500 women who received care during the intervention period. We calculated the required sample size based on an expected increase in antenatal contacts from 86.6 to 95.0% according to the finding of our formative study.[4] We considered a 95% confidence interval, 80% power, an intraclass correlation coefficient of 0.02675, and 10% attrition in the sample size calculation.[22] We performed two-stage random sampling to select 500 eligible women from each study site for the baseline and follow-up surveys accordingly.

For the first stage, we defined sub-districts as a cluster unit. A sub-district is composed of several administrative community units. We used the administrative community units as a primary sampling unit, and randomly selected primary sampling units from each sub-districts that corresponds to the probability proportionate to the population. For the second stage, we randomly selected 10 women per primary sampling unit.

Trained research assistants performed the survey by visiting the households of the eligible women and conducting face-to-face interviews with women who had no knowledge

about the cluster allocation. The structured questionnaire included women's socio-demographic characteristics; frequency and timing of contacts with health-care providers; contents of care that women and their newborn received during ANC, PPC, and PNC; and whether they received the CoC card. The frequency and timing of contacts and contents of care corresponded to the recommendation of the Ghana National Safe Motherhood Service Protocol.[23]

Main outcome measures

We defined adequate contacts based on the frequency and timing of contacts with health-care providers as follows: at least 4 contacts with health-care providers during pregnancy, delivery with assistance of skilled health-care providers at a health-care facility, and 3 contacts with health-care providers within 48 hours, at 1 week (3-10 days), and at 6 weeks (36-48 days) postpartum (Table 1).

We measured the quality of care based on the contents of care received by the women and their newborns during ANC, PPC, and PNC (Table 1). The process-of-care dimension in Donabedian's framework was employed.[7] We created quality of care indexes that consisted of 6 care items for ANC, 3 for PPC, and 14 for PNC. High-quality care was defined as receiving all care items during ANC, PPC, and PNC.

Having adequate contacts with health-care providers and high-quality care was considered the primary outcome, and the variable was composed of 3 categories: inadequate contacts regardless of care quality, adequate contacts with low-quality care, and adequate contacts with high-quality care. (i.e., quality-adjusted adequate contacts).

Table 1 Definitions of the study outcome

Stage	Contacts with health-care providers	Contents of care	Primary outcome
Antenatal care (ANC)	At least 4 contacts	6 care items: (1) HIV test (2) Hemoglobin test ≥2 (3) Tetanus toxoid vaccination ≥2 (4) Intermittent preventive treatment for malaria ≥3 (5) Blood group and Rhesus factor test (6) Blood pressure assessment ≥4	(i) Inadequate contacts: ≤3 contacts (ii) Adequate contacts with low quality: ≥4 contacts with ≤5 care items (iii) Adequate contacts with high quality (i.e., quality-adjusted adequate contacts): ≥4 contacts with 6 care items
Peripartum care (PPC)	Skilled facility-based delivery (SFD)	3 care items: (1) Dried newborn's body (2) Skin-to-skin contact (3) Initiation of breastfeeding ≤30 minutes	(i) Inadequate contact: Non-SFD (ii) Adequate contact with low quality: SFD with ≤2 care items (iii) Adequate contact with high quality (i.e., quality-adjusted adequate contact): SFD with 3 care items
Postnatal care (PNC)	3 contacts with timeliness: First: ≤ 48 hours Second: 3-10 days Third: 36-48 days	14 care items: Mother: (1) Temperature measurement (2) Blood pressure assessment (3) Bleeding check (4) Breastfeeding problem check (5) Hemoglobin assessment (6) Fundal height assessment (7) Perineum/Lochia check (8) Vitamin A supplement; Newborn: (9) General physical examination (10) BCG immunization (11) OPV immunization (12) Umbilical cord bleeding check (13) Temperature measurement (14) Breastfeeding difficulties check	(i) Inadequate contact: ≤2 contacts or non-timely contacts (ii) Adequate contacts with low quality: 3 timely contacts with ≤13 care items (iii) Adequate contacts with high quality (i.e., quality-adjusted adequate contacts): 3 timely contacts with 14 care items

Participants and Public involvement

Participants and public were not involved in the design of, the recruitment to, and conduct of the study because this was a randomized controlled trial. However, community people in the intervention group were announced about the EMBRACE project at the commencement of the trial.

Statistical analysis

We calculated the distributions of the basic characteristics of the women, the percentage of care items received by women and their newborns, and the proportions of adequate contacts with high quality care. We evaluated the effect of the intervention on receiving single-care items and having adequate contacts with high-quality care during ANC, PPC, and PNC. However, the effect of the intervention could be biased because of imbalanced cluster allocation; the effect could appear greater as 3 clusters with district hospitals were assigned to the intervention group. Moreover, women in the control group could access district hospitals in the intervention group, which in turn leads to a potential contamination that could make the effect of the intervention smaller. Thus, to control for these potential biases, we utilized difference-in-difference (DiD) analyses with 4 groups including the intervention (n=863) and control (n=617) groups in the baseline survey and the intervention (n=870) and control (n=602) groups in the follow-up survey. The DiD analyses adjusted a potential confounder of living in a cluster with a district hospital, and the effect of cluster correlations using robust variance estimates.

Furthermore, we evaluated the study outcome in the intention-to-treat and per-protocol designs. The intention-to-treat design focuses whether the intervention works in the real world setting, which shows effectiveness of the intervention.[24] Thus, we assigned the sample that corresponded to the initial cluster allocation, which results could be affected by coverage and contamination of the intervention. The per-protocol design focuses whether the intervention works in the ideal setting, which shows efficacious of the intervention.[24] Thus, we assigned the sample according to the possession of the CoC card in lieu of the actual enrolment to the

intervention group; we excluded 238 women in the intervention group who did not receive a CoC card, and 134 women in the control group who received a CoC card.

Finally, we performed logistic regression analysis to identify characteristics of women in the intervention group who had a greater chance of having adequate contacts with high-quality care using the follow-up survey data (n=870). The independent variables included study site, living in a sub-district with a district hospital, national health insurance membership, wealth quintiles according to the possession of the household assets, and parity. We employed robust variance estimate to control for potential correlations within clusters. We used Stata 13 (College Station, TX: Stata Corp LP) for the analyses.

Ethical approval

We obtained ethical approvals from Ghana Health Service, Navrongo HRC, Kintampo HRC, Dodowa HRC, and The University of Tokyo. Consent was obtained from the local health authorities and community leaders prior to conducting the intervention study. We obtained oral informed consent from participants of the intervention, whereas we obtained written informed consent from participants of the surveys. For those who were aged under 18, we requested permission from their guardians and obtained their signature on the consent form.

RESULTS

We analyzed the baseline survey data of 1,480 women and the follow-up survey data of 1,490 women. In the baseline survey, 617 (41.7%) were sampled from the control group, and 863 (58.3%) were sampled from the intervention group. In the follow-up survey, 620 (41.6%) were sampled from the control group, and 870 (58.4%) were sampled from the intervention group. In addition, we excluded the data of 10 women in one primary sampling unit from the baseline and follow-up survey datasets accordingly, because it did not have 10 eligible women during the follow-up survey.

Table 2 shows the distributions of the basic characteristics of the women. The intervention group had more Muslim and wealthy women than the control group.

Table 2 Basic characteristics of women (n=2970)

	Baseline (n=1,480)					Follow-up (n=1,490)				
	Control (n=617)		Intervention (n=863)			Control (n=620)		Intervention (n=870)		
	n	(%)	n	(%)	*p*	n	(%)	n	(%)	*p*
Study site										
Navrongo	220	(35.7)	280	(32.4)	0.43	220	(35.5)	280	(32.2)	0.40
Kintampo	198	(32.1)	288	(33.4)		200	(32.3)	290	(33.3)	
Dodowa	199	(32.3)	295	(34.2)		200	(32.3)	300	(34.5)	
Age										
≤19	35	(5.7)	53	(6.1)	0.83	92	(14.8)	130	(14.9)	0.93
20-34	452	(73.3)	638	(73.9)		439	(70.8)	621	(71.4)	
35-49	130	(21.1)	172	(19.9)		89	(14.4)	119	(13.7)	
Education										
Did not complete primary	178	(28.9)	257	(29.8)	0.77	145	(23.4)	182	(20.9)	0.12
Completed primary	170	(27.6)	222	(25.7)		196	(31.6)	242	(27.8)	
Completed secondary	209	(33.9)	289	(33.5)		207	(33.4)	326	(37.5)	
Complete tertiary	60	(9.7)	95	(11.0)		72	(11.6)	120	(13.8)	
Marital status										
Married	415	(67.3)	542	(62.8)	0.12	351	(56.6)	470	(54.0)	0.32
Cohabitating	150	(24.3)	224	(26.0)		163	(26.3)	260	(29.9)	
Other	52	(8.4)	97	(11.2)		106	(17.1)	140	(16.1)	
Parity										
Once	128	(20.8)	196	(22.7)	0.37	187	(30.2)	299	(34.4)	0.09
Twice or more	489	(79.3)	667	(77.3)		433	(69.8)	571	(65.6)	
Religion										
Christian	524	(84.9)	656	(76.0)	<0.01	533	(86.0)	682	(78.4)	<0.01
Muslim	51	(8.3)	150	(17.4)		65	(10.5)	145	(16.7)	
Others	42	(6.8)	57	(6.6)		22	(3.6)	43	(4.9)	
Wealth quintiles										
Lowest	144	(23.3)	156	(18.1)	<0.01	171	(27.6)	188	(21.6)	<0.01
Lower	141	(22.9)	155	(18.0)		132	(21.3)	112	(12.9)	
Middle	104	(16.9)	196	(22.7)		118	(19.0)	174	(20.0)	
Higher	120	(19.5)	169	(19.6)		106	(17.1)	192	(22.1)	
Highest	108	(17.5)	187	(21.7)		93	(15.0)	204	(23.5)	
National health insurance										

Covered	344	(55.8)	510	(59.1)	0.21	407	(65.7)	611	(70.2)	0.06
Not covered	272	(44.2)	353	(40.9)		213	(34.4)	259	(29.8)	

p, p-value for chi-squared test.

Table 3 shows the contents of care received by the women and their newborns during ANC, PPC, and PNC. After the intervention, 12.6% of women in the intervention group received all 6 items during ANC, 33.6% received all 3 items during PPC, and 41.5% of women and their newborns received all 14 items during PNC with no significant difference in DiD analysis. Among the 4 ANC care items which reception were recorded in the CoC card, blood group testing was significantly increased to 79.5% in the intervention group. For other care items, the percentage remained low even after the intervention: hemoglobin tests (40.9%), intermittent preventive treatment for malaria (43.7%), and tetanus toxoid vaccination (46.4%). During the peripartum period, only 47.0% initiated breastfeeding within the first 30 minutes. During PNC, over 60% of women and their newborns received each care item.

Table 3 Content of ANC, PPC, and PNC (n=2,970)

	Baseline				Follow-up					
	Control (n=617)		Intervention (n=863)		Control (n=620)		Intervention (n=870)			
	n	(%)	n	(%)	n	(%)	n	(%)	DiD†	*p*
ANC										
All 6 care items received	35	(5.7)	42	(4.9)	66	(10.7)	110	(12.6)	2.7	0.54
Blood group and Rhesus factor test	326	(52.8)	431	(49.9)	421	(67.9)	692	(79.5)		
HIV test	364	(59.0)	480	(55.6)	494	(79.7)	675	(77.6)		
Blood pressure assessment 4 times	341	(55.3)	444	(51.5)	443	(71.5)	630	(72.4)		
Tetanus toxoid vaccination 2 doses	252	(40.8)	339	(39.3)	343	(55.3)	404	(46.4)		
Intermittent preventive treatment for malaria 3 doses	249	(40.4)	313	(36.3)	274	(44.2)	380	(43.7)		
Hemoglobin test 2 times	178	(28.9)	228	(26.4)	222	(35.8)	356	(40.9)		
PPC										
All 3 care items received	150	(24.3)	205	(23.8)	197	(31.8)	292	(33.6)	2.3	0.71
Dried newborn's body	542	(87.8)	777	(90.0)	584	(94.2)	812	(93.3)		
Skin-to-skin contact	295	(47.8)	396	(45.9)	365	(58.9)	528	(60.7)		

Initiation of breastfeeding ≤30 minutes	277	(44.9)	336	(38.9)	287	(46.3)	409	(47.0)		
PNC										
All 14 care items received	63	(10.2)	99	(11.5)	197	(31.8)	361	(41.5)	8.4	0.36
Mother										
All 8 maternal care items received	131	(21.2)	194	(22.5)	218	(35.2)	415	(47.7)	11.3	0.14
Temperature measurement	404	(65.5)	563	(65.2)	430	(69.4)	679	(78.1)		
Blood pressure assessment	310	(50.2)	408	(47.3)	431	(69.5)	668	(76.8)		
Bleeding check	325	(52.7)	505	(58.5)	429	(69.2)	638	(73.3)		
Breastfeeding problem check	286	(46.4)	452	(52.4)	414	(66.8)	626	(72.0)		
Vitamin A supplement	364	(59.0)	498	(57.7)	365	(58.9)	595	(68.4)		
Fundal height measurement	306	(49.6)	443	(51.3)	341	(55.0)	559	(64.3)		
Perineum/lochia check	293	(47.5)	461	(53.4)	357	(57.6)	550	(63.2)		
Hemoglobin assessment	299	(48.5)	422	(48.9)	317	(51.1)	537	(61.7)		
Newborns										
All 6 newborn care items received	81	(13.1)	175	(20.3)	326	(52.6)	506	(58.2)	-1.6	0.87
General physical examination	443	(71.8)	595	(69.0)	464	(74.8)	678	(77.9)		
Temperature measurement	99	(16.1)	214	(24.8)	442	(71.3)	661	(76.0)		
Breastfeeding difficulties check	293	(47.5)	492	(57.0)	440	(71.0)	642	(73.8)		
Umbilical cord bleeding check	302	(49.0)	496	(57.5)	443	(71.5)	638	(73.3)		
OPV immunization	412	(66.8)	519	(60.1)	412	(66.5)	595	(68.4)		
BCG immunization	391	(63.4)	522	(60.5)	372	(60.0)	559	(64.3)		

[†]Potential effect of cluster correlations was adjusted using robust variance estimates. Living in a cluster with district hospital was included in the model due to potential confounder.

DiD, difference-in-difference estimator; *p,* p-value for DiD estimators.

Table 4 shows the effect of the intervention on having adequate contacts with high-quality care. After the intervention, 12.6% of women in the intervention group had adequate contacts with high-quality care during ANC, with no significant effect in the intention-to-treat design (DiD=2.7, p=0.54) and per-protocol design (DiD=3.2, p=0.52). During PPC, 31.5% of women in the intervention group had adequate contacts with high-quality care, with no significant effect in the intention-to-treat design (DiD=2.0, p=0.73) and per-protocol design (DiD=7.4, p=0.27). During PNC, 33.7% of women in the intervention group had adequate contacts with high-quality care, with no significant effect in the intention-to-treat design

(DiD=12.7, p=0.14), but with a significant effect in the per-protocol design (DiD=20.7, p=0.01).

Additionally, Table 4 shows the gap between adequate contacts (i.e., adequate contacts with high- or low-quality care) and quality-adjusted adequate contacts (i.e., adequate contacts with high-quality care). In the intention-to-treat design, 76.9% of women in the intervention group in the follow-up survey had adequate contacts during ANC; however, only 12.6% had quality-adjusted adequate contacts. Moreover, 82.0% delivered with the assistance of a skilled birth attendant at a health-care facility, while only 31.5% had a skilled delivery with high-quality care. During PNC, 62.2% of women had adequate contacts. However, only 33.7% had quality-adjusted adequate contacts.

Table 4 Effect of intervention on having adequate contacts with high-quality care

	Baseline (n=1,480)				Follow-up: Intention to treat (n=1,490)						Follow up: Per protocol (n=1,118)					
	Control (n=617)		Intervention n=863		Control (n=620)		Intervention (n=870)				Control (n=486)		Intervention (n=632)			
	n	(%)	n	(%)	n	(%)	n	(%)	DiD[†]	*p*	n	(%)	n	(%)	DiD	*p*
ANC																
Inadequate contacts	202	(32.7)	273	(31.6)	141	(22.7)	201	(23.1)	-	-	115	(23.7)	139	(22.0)	-	-
Adequate contacts with low quality	380	(61.6)	548	(63.5)	413	(66.6)	559	(64.3)	-	-	323	(66.5)	411	(65.0)	-	-
Adequate contacts with high quality	35	(5.7)	42	(4.9)	66	(10.7)	110	(12.6)	2.7	0.54	48	(9.9)	82	(13.0)	3.2	0.52
PPC																
Inadequate contact	154	(25.0)	231	(26.8)	124	(20.0)	157	(18.1)	-	-	110	(22.6)	96	(15.2)	-	-
Adequate contact with low quality	334	(54.1)	458	(53.1)	309	(49.8)	439	(50.5)	-	-	243	(50.0)	320	(50.6)	-	-
Adequate contact with high quality	129	(20.9)	174	(20.2)	187	(30.2)	274	(31.5)	2.0	0.73	133	(27.4)	216	(34.2)	7.4	0.27
PNC																
Inadequate contacts	538	(87.2)	749	(86.8)	281	(45.3)	329	(37.8)	-	-	234	(48.2)	203	(32.1)	-	-
Adequate contacts with low quality	61	(9.9)	103	(11.9)	199	(32.1)	248	(28.5)	-	-	160	(32.9)	188	(29.8)	-	-
Adequate contacts with high quality	18	(2.9)	11	(1.3)	140	(22.6)	293	(33.7)	12.7	0.14	92	(18.9)	241	(38.1)	20.7	0.01

[†]Potential effect of cluster correlations was adjusted using robust variance estimates. Living in a cluster with district hospital was included as a potential confounder in the model.

DiD, difference-in-difference estimator; *p*, p-value for DiD estimators.

Table 5 shows variations in having adequate contacts with high-quality care according to the characteristics of women in the intervention group in the follow-up survey. Women living in Navrongo were more likely to have adequate contacts with high-quality care during PPC and PNC than women living in Kintampo (AOR=0.24; 95% CI 0.10 to 0.54 at PPC, AOR=0.08; 95% CI 0.04 to 0.16 at PNC) and in Dodowa (AOR=0.19; 95% CI 0.09 to 0.38 at PPC; AOR=0.37; 95% CI 0.23 to 0.58 at PNC). During ANC, however, women living in Dodowa were more likely to have adequate contacts with high-quality care (AOR=2.75; 95% CI 1.49 to 5.06) than those living in Navrongo. Women with national health insurance membership were more likely to have adequate contacts with high-quality care during ANC (AOR=1.93; 95% CI 1.27 to 2.92) and PNC (AOR=1.46; 95% CI 1.12 to 1.89) than those without membership. Compared with women in the lowest wealth group, those in the highest wealth group were more likely to have adequate contacts with high-quality care during ANC (AOR=2.29; 95% CI 1.15 to 4.57) and PNC (AOR=1.83; 95% CI 1.04 to 3.23), and women in the lower wealth group were more likely to have adequate contacts with high-quality care during PPC (AOR=1.68; 95% CI 1.09 to 2.59). Women who had delivered at least twice were more likely to have adequate contacts with high-quality care during ANC than primiparous women (AOR=1.79, 95% CI 1.16 to 2.75).

Table 5 Factors associated with adequate contacts with high-quality care in the intervention group of the follow-up survey (n=870)

	ANC		PPC		PNC	
	AOR	(95% CI)	AOR	(95% CI)	AOR	(95% CI)
Study site						
Navrongo	1.00		1.00		1.00	
Kintampo	0.72	(0.38-1.36)	0.24	(0.10-0.54)	0.08	(0.04-0.16)
Dodowa	2.75	(1.49-5.06)	0.19	(0.09-0.38)	0.37	(0.23-0.58)
Living near a district hospital						
Yes	1.46	(0.78-2.73)	1.60	(0.83-3.09)	1.10	(0.70-1.74)
No	1.00		1.00		1.00	

National health insurance						
Covered	1.93	(1.27-2.92)	1.18	(0.76-1.81)	1.46	(1.12-1.89)
Not covered	1.00		1.00		1.00	
Wealth quintiles						
Lowest	1.00		1.00		1.00	
Lower	0.66	(0.24-1.78)	1.68	(1.09-2.59)	1.14	(0.79-1.65)
Middle	0.85	(0.31-2.31)	1.37	(0.78-2.40)	0.84	(0.51-1.37)
Higher	2.16	(0.96-4.89)	1.33	(0.71-2.46)	1.09	(0.66-1.80)
Highest	2.29	(1.15-4.57)	1.14	(0.61-2.11)	1.83	(1.04-3.23)
Parity						
Once	1.00		1.00		1.00	
Twice or more	1.79	(1.16-2.75)	1.25	(0.91-1.72)	0.92	(0.59-1.41)

Potential effect of cluster correlations was adjusted using robust variance estimates.

AOR, adjusted odds ratios by multiple logistic regression analyses.

DISCUSSION

A 12-month implementation of the intervention showed significant effects on high quality care during regular contacts with health-care providers at PNC in the per-protocol design. In the intention-to-treat design, however, the intervention showed no significant effects during ANC, PPC, and PNC. In addition, a large gap remained between the crude contacts and quality-adjusted contacts. Hence, despite strengthening regular contacts with health-care providers through the intervention, women and their newborns did not receive high-quality care. Furthermore, a chance to have adequate contacts and receive high-quality care varied among women with different socio-demographic backgrounds (i.e. residential area, and membership of national health insurance) in the intervention group.

The results showed the intervention was efficacious in increasing postnatal contacts and improving the quality of care among those who actually received it, but did not provide evidence of

the effectiveness. Before implementing the intervention, we found that the women were not aware of the importance of PNC, and they believed in a local custom that women and their newborns should stay at home for 6 weeks postpartum. As shown in other intervention studies,[25,26] this intervention targeted to improve women's motivation and health-care' provider's knowledge. Using the CoC card, women learned the importance and timings of PNC during ANC, and were given specific appointments for PNC visits. Health-care providers received a three-day training course and a monthly supervision from the district health management team. The result indicates that the intervention was efficacious, but did not reach all women equally.

The intervention showed no significant effect on ANC. Only 12.6% of women in the intervention group had adequate contacts and received high-quality care. Low coverage of hemoglobin assessment, tetanus toxoid vaccination, and intermittent preventive treatment for malaria could result in low-quality care during ANC. During the intervention, we addressed these challenges by tracking the use of these care items and blood group test using the CoC card. After the intervention, blood group test significantly increased, whereas other care items did not change significantly. One possible explanation was that pregnant women were required to receive those care items multiple times. The percentage of women who had adequate contacts with high-quality care during ANC was higher in Dodowa (23.7%) than in Navrongo (9.3%) and Kintampo (4.5%). A potential explanation is that Dodowa has geographical advantages in procuring or accessing essential medicines and equipment for ANC as it is a part of Greater Accra region.

Women living in Navrongo were more likely to have adequate contacts with health-care providers and receive high-quality care during PPC and PNC than those living in Kintampo and Dodowa, which suggests that the intervention package works effectively through the advanced primary health-care system in Navrongo. In Ghana, CHPS initiatives developed a community-based primary health-care system.[19] The initiatives was first introduced in Navrongo in 1994, and scaled-

up across the country.[19] However, the health system remains underdeveloped in most parts of the country, including Dodowa and Kintampo. Unequal assignment of midwives among the 3 study sites is a typical example, which could affect the availability and quality of maternal and newborn care. The intervention package could work more effectively in an improved health system.

Women covered by the national health insurance were more likely to have adequate contacts and receive high-quality care during ANC and PNC, whereas women in the lowest wealth group were less likely to have adequate contacts with high-quality care during ANC and PNC compared with women in the highest wealth group. This highlights the importance of the national health insurance. Women with insurance membership could benefit from a free package of ANC, delivery, and PNC services with an annual premium of 12 Ghana Cedi (or around 2.7 USD).[27] However, only 63% of the women in this study had insurance membership. The evidence presented in this study would be useful in advocating for the enrollment of more women in the national health insurance scheme.

Limitations

This study has several limitations. First, cluster allocation was uneven, which could affect the implementation and effect of the intervention. The implementation in the intention-to-treat design allowed women to choose and utilize any health-care facilities across the clusters, which could also influence the effect of the intervention. Second, the study sites had been exposed to various research projects.[28-31] The effects of our intervention could be built on the effects of previous projects. Third, no standardized measurements for the quality of ANC, PPC, and PNC are available. Each quality of care index consists of different number of items. Moreover, although the value of each item was not equal, we treated all items with an equal weight. Thus, comparing the quality of care among ANC, PPC, and PNC would not be appropriate.

CONCLUSION

The intervention package for strengthening the continuum of care showed a significant effect on contacts with health-care providers and the quality of care in PNC, but not in ANC and PPC. Women and their newborns did not receive high-quality care during the regular contacts with health-care providers. The intervention package could work more effectively under a well-developed community-based health-care system and with broader national health insurance coverage. Ensuring adequate contacts with health-care providers and improving quality of care are both vital in promoting maternal and newborn health in Ghana.

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Competing interests

All authors received the grant from Human Development Division, Japan International Cooperation Agency for implementing and evaluating this trial; no financial relationships with any organizations that might have an interest in this work in the previous 4 years; no other relationships or activities that could appear to have influenced this work.

Authors' contribution

SO, MG, AS, KK, FY, CT, SA, KN, ARO, SOA, EKA, GQA, JY, AH, and MJ contributed to the conception and design of the study. SO, MG, FY, CT, SA, ARO, and SOA conducted interventions and collected data. SO, AS, KK, EKA, AH, and MJ interpreted data. SO conducted statistical

analysis and drafted manuscript. SO, MG, HHL, and MJ contributed to the revision of manuscript. All authors approved the final version of the manuscript. AH and MJ are the study guarantor.

Patient consent

The study was approved by the Ethics Review Committee of Ghana Health Service, the Institutional Review Boards of Dodowa HRC and Navrongo HRC, the Institutional Ethics Committee of Kintampo HRC in Ghana, and the Research Ethics Committee of the University of Tokyo in Japan. At the enrolment of the baseline and follow-up surveys, we obtained written informed consent from the women. If the women were under the age of 18, we requested permission from their guardians and obtained their signature on the consent form. At the study enrolment, we obtained oral informed consent from the women to receive the interventions. The study protocol was registered in the ISRCTN Registry (90618993).

Data sharing

The datasets used and/or analyzed during the current study are available on reasonable request from the corresponding author (MJ) under permission by all relevant ethics committees.

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5-6
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	7,8
	4b	Settings and locations where the data were collected	6,7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7,8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9,10, Table1
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11-12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11-12
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12
	13b	For each group, losses and exclusions after randomisation, together with reasons	12
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	7
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	13, Table2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	12
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	12-17, Tables 2,3,4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	18,19, Table5
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	15-17, Table4
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	21
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19-21
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19-21
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	Referenece22
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	22

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Effect of continuum-of-care intervention package on improving contacts and quality of maternal and newborn health care in Ghana: a cluster randomized controlled trial

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Effect of continuum-of-care intervention package on improving contacts and quality of maternal and newborn health care in Ghana: a cluster randomized controlled trial

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ABSTRACT

Objective: To evaluate the effect of a continuum-of-care intervention package on adequate contacts of women and newborn with healthcare providers and their reception of high-quality care.

Design: Cluster randomized controlled trial.

Setting: 32 sub-districts in 3 rural sites in Ghana.

Participants: The baseline survey involved 1,480 women who delivered before the intervention, and the follow-up survey involved 1,490 women who received maternal and newborn care during the trial.

Interventions: The intervention package included: training healthcare providers, utilizing an educational and recording tool named "continuum-of-care card", providing the first postnatal care (PNC) by retaining women and newborns at healthcare facility or home visit by healthcare providers.

Outcome measures: Adequate contacts were defined as at least 4 contacts during pregnancy, delivery with assistance of skilled healthcare providers at a healthcare facility, and 3 timely contacts within 6 weeks postpartum. High-quality care was defined as receiving 6 care items for antenatal care (ANC), 3 for peripartum care (PPC), and 14 for PNC.

Results: The difference-in-difference method was used to assess the effects of the intervention on the study outcome. The percentage of adequate contacts with high-quality care in the intervention group in the follow-up survey and the adjusted difference-in-difference estimators were 12.6% and 2.2 (p=0.61) at ANC, 31.5% and 1.9 (p=0.73) at PPC, and 33.7% and 12.3 (p=0.13) at PNC in the intention-to-treat design, whereas 13.0% and 2.8 (p=0.54) at ANC, 34.2% and 2.7 (p=0.66) at PPC, and 38.1% and 18.1 (p=0.02) at PNC in the per-protocol design that assigned the study sample by possession of the continuum-of-care card.

Conclusions: The interventions improved contacts with healthcare providers and quality of care during PNC. However, having adequate contact did not guarantee high-quality care. Maternal and newborn care in Ghana needs to improve its continuity and quality.

Trial registration number: (90618993)

Strengths and Limitations

- This was a cluster randomized controlled trial conducted in three rural sites which had diverse socio-economic and ecological backgrounds and operated the Health and Demographic Surveillance System.
- This study assessed the effect of the intervention on having adequate contact of women and their newborns with healthcare providers and their reception of high-quality care in antenatal, peripartum, and postnatal care.
- The results showed that regular contacts with healthcare providers did not guarantee quality of care, although the results could be affected by uneven cluster allocation and contamination.
- Maternal and newborn care program needs to improve continuity and quality of care in Ghana.

INTRODUCTION

Maternal and newborn health has significantly improved during the Millennium Development Goals era. Women and newborns still encounter a life-threatening risk from the third trimester to the first month postpartum in resource limited countries.[1, 2] A key strategy to maintain maternal and neonatal health throughout the high risk period is to provide effective interventions continuously during the high-risk period,[3] namely Continuum of Care (CoC). However, CoC remains a critical challenge in many countries. In our previous study, for example, only 8% of women completed CoC from pregnancy to postpartum period.[4] Moreover, regular contacts with healthcare providers alone would not improve maternal and newborn health outcomes if they did not receive quality care.[5]

Maternal and newborn health research provides no comprehensive definition and measurements of quality of care when we designed this study.[6] In 1988, Donabedian suggested a framework for quality of care assessment.[7] In the framework, quality of care is assessed with 3 dimensions: structure, process, and outcomes.[7] Using this framework, existing literature measured quality of care by creating composite indexes of structure and/or process of care,[8-11] and identified remarkable gaps between contacts with healthcare providers and actual quality of care during the contacts.[9, 10, 12, 13] In addition, previous studies evaluated the effects of interventions on improving process of care (e.g., receiving iron tablets, tetanus toxoid injections, HIV testing, intermittent preventive treatment for malaria, or basic newborn care).[14-16] However, to our best knowledge, few intervention studies have evaluated the effects of interventions on both contacts with healthcare providers and quality of care from pregnancy to the postpartum period.

Ghana is one of the sub-Saharan African countries with an estimated maternal mortality ratio of 380/100,000 live births in 2013.[17] Neonatal mortality rate was 29/1,000 live births in 2010-2014, with a minor reduction in the last decade.[18] The government of Ghana introduced health policies to mitigate the financial and geographical constraints affecting the access to

healthcare services: community-based health planning and services (CHPS) initiative in 1999,[19] and national health insurance scheme in 2004.[20] In this scheme, pregnant women are able to obtain their health insurance which includes a free package of ANC, delivery, caesarean section, and PNC services without paying the annual premium and processing fees.[21, 22] Our previous studies showed that women with national health insurance were more likely to have four ANC visits and deliver at a healthcare facility.[23, 24] Despite improvements in coverage for maternal and child health, further effort is needed to strengthen the CoC and improve the quality of care under the implementation of these policies.

Ghana's Ensure Mothers and Babies Regular Access to Care (EMBRACE) implementation research aimed to strengthen CoC.[25] The major activities included the development and implementation of an intervention package and evaluation of its effect on CoC. Based on the findings of formative research,[4] we developed an intervention package to ensure CoC with healthcare providers during ANC, peripartum care (PPC), and PNC. Although CoC is the primary outcome for the impact evaluation,[26] quality of care during the regular contacts is another important outcome for the process evaluation, which provides multifaceted implications for maternal and newborn health program. Therefore, the objectives of this study were to examine the effects of the CoC intervention package on having adequate contacts with healthcare providers and high-quality care by the mothers and their newborns compared to the standard maternal and newborn care under the national guidelines, and to determine the factors associated with having adequate contacts with high-quality care among those in the intervention group in the follow-up survey.

METHODS

Study design and setting

This was a cluster randomized controlled trial using the effectiveness-implementation hybrid design registered in ISRCTN (90618993).[26] In order to enhance the generalizability of study

findings in rural setting of Ghana, we selected 3 rural sites: Navrongo (northern), Kintampo (central), and Dodowa (southern) which had diverse socio-economic and ecological background and health systems challenges. Additionally, these study sites had Health Research Centers (HRCs) under the Ghana Health Service, and these HRCs operated the Health and Demographic Surveillance System. Such research infrastructure could be beneficial for the quality control of the intervention and surveys.

Each study site covered 2 districts and consisted of 36 sub-districts. We included 32 sub-districts in this study (Navrongo, 12; Kintampo, 12; and Dodowa, 8) and excluded 4 sub-districts because of other projects implemented or planned during our intervention period. We used sub-district as a cluster unit as it was the primary unit of the health system. In the pre-intervention facility assessment, the percentage of healthcare facilities with at least one midwife was 47% in Navrongo, 36% in Dodowa, and 21% in Kintampo.

We made 16 pairs of the clusters (Navrongo, 6; Kintampo 6; and Dodowa, 4), taking into account the population, the volume of delivery, and the number of midwives in each cluster. Then, we randomly assigned the clusters within a pair to the intervention or the control groups. A data analyst who was not a member of the study team randomly allocated the paired clusters using computer-generated random sequences. However, we assigned 3 clusters with a district hospital to the intervention group as majority of the childbirths took place in these hospitals. We informed about the implementation of the intervention to the community people and healthcare providers in the intervention group only. However, complete blinding was not feasible; we implemented the intervention in the intention-to-treat design, which did not control for women's choice and access to healthcare facilities across a cluster boundary.

Participants and intervention

Women who were aged between 15 – 49 years old, and delivered between October 1, 2014 and September 30, 2015 in the intervention group were eligible for study enrolment.[26]

We implemented the intervention for 12 months (October 1, 2014 to September 30, 2015) as initially planned in the protocol. The details of the intervention were described previously.[26] Women were enrolled to the intervention when they had contacts with healthcare providers anytime from pregnancy to the postpartum period.

The intervention package was composed of 4 interventions. First, healthcare providers underwent reorientation about CoC. Second, healthcare providers distributed the CoC card to women, which contains the schedule and actual dates of contacts with healthcare providers, information on essential care and birth preparedness, and the presence of danger signs. Healthcare providers and women utilized the CoC card in every contact. Third, healthcare providers retained women and their newborns in the healthcare facility for the first 24 hours postpartum to provide the first PNC. Fourth, healthcare providers made home visits to provide PNC to women and their newborns within the first 48 hours if they missed the first postnatal contact by 24 hours postpartum.

We emphasized to implement the intervention using the existing health systems and resource; all intervention facilities in the 3 sites had re-orientation of healthcare providers, and implemented all or a part of the intervention package depending on availability of resource and infrastructure. In addition, district health management teams conducted monthly supervision in healthcare facilities, monitored the performance of the interventions, and had a monthly meeting to report the progress and discuss the challenges in collaboration with research teams. In the control group, women and their newborns received the standard care recommended by the Ghana National Safe Motherhood Service Protocol.[27] During the trial period, we did not observe any harms or unintended events in the intervention or the control groups.

Survey

We conducted the baseline survey from July to September 2014, with a sample of 1,500 women who delivered between September 1, 2012 and June 30, 2014, and the follow-up survey was performed from October to December 2015, with a sample of 1,500 women who received care

during the intervention period. We calculated the required sample size based on an expected increase in antenatal contacts from 86.6 to 95.0% according to the finding of our formative study.[4] We considered a 95% confidence interval, 80% power, an intraclass correlation coefficient of 0.02675, and 10% attrition in the sample size calculation.[26] We performed two-stage random sampling to select 500 eligible women from each study site for the baseline and follow-up surveys.

For the first stage, we defined sub-districts as a cluster unit. A sub-district is composed of several administrative community units. We used the administrative community units as a primary sampling unit, and randomly selected primary sampling units from each sub-district that corresponded to the probability proportionate to the population. For the second stage, we randomly selected 10 women per primary sampling unit.

Trained research assistants performed the survey by visiting the households of the eligible women and conducting face-to-face interviews with women who had no knowledge about the cluster allocation. The structured questionnaire included women's socio-demographic characteristics; frequency and timing of contacts with healthcare providers; contents of care that women and their newborn received during ANC, PPC, and PNC; and whether they received the CoC card. The frequency and timing of contacts and contents of care corresponded to the recommendation of the Ghana National Safe Motherhood Service Protocol.[27]

Main outcome measures

We defined adequate contacts based on the frequency and timing of contacts with healthcare providers as follows: at least 4 contacts with healthcare providers during pregnancy, delivery with assistance of skilled healthcare providers at a healthcare facility, and 3 contacts with healthcare providers within 48 hours, at 1 week (3-10 days), and at 6 weeks (36-48 days) postpartum (Table 1).

We measured the quality of care based on the contents of care received by the women and their newborns during ANC, PPC, and PNC (Table 1). The process-of-care dimension in

Donabedian's framework was employed.[7] We created quality of care indexes that consisted of 6 care items for ANC, 3 for PPC, and 14 for PNC. High-quality care was defined as receiving all care items during ANC, PPC, and PNC.

Having adequate contacts with healthcare providers and high-quality care was considered as the primary study outcome. The variable was composed of 3 categories: inadequate contacts regardless of care quality, adequate contacts with low-quality care, and adequate contacts with high-quality care. (i.e., quality-adjusted adequate contacts).

Table 1 Definitions of the study outcome

Stage	Contacts with healthcare providers	Contents of care	Primary outcome
Antenatal care (ANC)	At least 4 contacts	6 care items: (1) HIV test (2) Hemoglobin test ≥2 (3) Tetanus toxoid vaccination ≥2 (4) Intermittent preventive treatment for malaria ≥3 (5) Blood group and Rhesus factor test (6) Blood pressure assessment ≥4	(i) Inadequate contacts: ≤3 contacts (ii) Adequate contacts with low-quality care: ≥4 contacts with ≤5 care items (iii) Adequate contacts with high- quality care (i.e., quality-adjusted adequate contacts): ≥4 contacts with 6 care items
Peripartum care (PPC)	Skilled facility-based delivery (SFD)	3 care items: (1) Dried newborn's body (2) Skin-to-skin contact (3) Initiation of breastfeeding ≤30 minutes	(i) Inadequate contact: Non-SFD (ii) Adequate contact with low-quality care: SFD with ≤2 care items (iii) Adequate contact with high-quality care (i.e., quality-adjusted adequate contact): SFD with 3 care items
Postnatal care (PNC)	3 contacts with timeliness: First: ≤ 48 hours Second: 3-10 days Third: 36-48 days	14 care items: Mother: (1) Temperature measurement (2) Blood pressure assessment (3) Bleeding check (4) Breastfeeding problem check (5) Hemoglobin assessment (6) Fundal height assessment (7) Perineum/Lochia check (8) Vitamin A supplement; Newborn: (9) General physical examination (10) BCG immunization (11) Oral polio vaccine (OPV) (12) Umbilical cord bleeding check (13) Temperature measurement (14) Breastfeeding difficulties check	(i) Inadequate contact: ≤2 contacts or non-timely contacts (ii) Adequate contacts with low-quality care: 3 timely contacts with ≤13 care items (iii) Adequate contacts with high-quality care (i.e., quality-adjusted adequate contacts): 3 timely contacts with 14 care items

Confounders

We considered the following variables as potential confounders: study site, living in a sub-district with a district hospital, age, education, marital status, parity, religion, wealth quintile index, and the status of national health insurance membership. Of these variables, age and parity were initially continuous variables, and converted to categorical variables: age (≤19, 20-34, and ≥35-49), parity (primipara and multipara). The variable of wealth quintile index was generated by performing principal component analysis of 13 household assets.

Statistical analysis

We calculated the distributions of the basic characteristics of the women, the percentage of each care item received by women and their newborns, and the percentage of having adequate contacts with healthcare providers and high-quality care. We evaluated the effect of the intervention on adequate contacts with high-quality care during ANC, PPC, and PNC. However, the effect of the intervention could be biased because of imbalanced cluster allocation; the effect could appear greater as 3 clusters with district hospitals were assigned to the intervention group. Moreover, women in the control group could access district hospitals in the intervention area, which in turn lead to a potential contamination that could make the effect of the intervention smaller. Thus, to control for these potential biases, we utilized the difference-in-difference (DiD) method with 4 groups including the intervention (n=863) and control (n=617) groups in the baseline survey and the intervention (n=870) and control (n=602) groups in the follow-up survey. Before performing the DiD analysis, we assessed two assumptions. First, no time-varying difference existed between the intervention and the control groups.[28] We did not observe any specific changes that might have affected the study outcome in both groups during the trial period. Second, the outcome trend should be equal in the intervention and the control groups in the absence of the trial.[28] However, it was not feasible to measure the change that could have occurred in the intervention group in the absence of the intervention because we did not conduct any surveys before the baseline survey. Therefore, we performed the DiD analysis

with cluster robust estimators of variance, controlling for individual characteristics. Robust estimators of variance is a technique used to estimate cluster robust standard errors and adjust the confidence intervals of the DiD estimators when the regression model is potentially affected by cluster correlations.[29]

We also considered the potential effect of contaminations. Therefore, we calculated DiD estimators in the intention-to-treat and per-protocol designs separately. The intention-to-treat design focuses whether the intervention works in the real world setting, which shows effectiveness of the intervention.[30] In the intention-to-treat analysis, we compared the percentages of the study outcomes between the intervention and the control groups corresponded to the initial cluster allocation. The results could be affected by coverage and contamination of the intervention. The per-protocol design focuses whether the intervention works in the ideal setting, which shows the efficacy of the intervention.[30] In the per-protocol analysis, we treated the possession of the CoC card as actual participation in the intervention. Thus, women in the intervention group who did not receive the CoC card and women in the control group who received the CoC card were excluded from the DiD analysis.

Finally, we performed sub-group analyses to identify factors associated with having adequate contacts with high-quality care among women in the intervention group in the follow-up survey (n=870). This analysis focused on identifying the characteristics of women who had greater chances of having adequate contacts with high-quality care in the intervention area. We used multivariable logistic regression with cluster robust standard errors. The independent variables were study site, living in a sub-district with a district hospital, age, education, marital status, parity, religion, wealth quintiles, and the status of national health insurance membership. We used Stata 13 (College Station, TX: Stata Corp LP) for the analyses.

Participants and Public involvement

Participants and public were not involved in the design of, the recruitment to, and conduct of the study because this was a randomized controlled trial. However, community people in the

intervention group were announced about the EMBRACE project at the commencement of the trial.

Ethical approval

We obtained ethical approvals from Ghana Health Service, Navrongo HRC, Kintampo HRC, Dodowa HRC, and The University of Tokyo. Consent was obtained from the local health authorities and community leaders prior to conducting the intervention study. We obtained oral informed consent from participants of the intervention, whereas we obtained written informed consent from participants of the surveys. For those who were aged under 18, we requested permission from their guardians and obtained their signature on the consent form.

RESULTS

We analyzed the baseline survey data of 1,480 women and the follow-up survey data of 1,490 women. The baseline survey dataset included 617 women (41.7%) in the control group and 863 women (58.3%) in the intervention group. The follow-up survey dataset included 620 (41.6%) in the control group and 870 (58.4%) in the intervention group. We excluded the data of 10 women from the baseline survey because they did not meet the inclusion criteria. Additionally, we excluded 10 women from the primary sampling unit at baseline and another 10 women from the primary sampling unit of the follow-up survey.

Table 2 shows the distributions of the basic characteristics of the women. The intervention group had more Muslim and wealthy women than the control group.

Table 2 Basic characteristics of women (n=2970)

	Baseline (n=1,480)					Follow-up (n=1,490)				
	Control (n=617)		Intervention (n=863)			Control (n=620)		Intervention (n=870)		
	n	(%)	n	(%)	p	n	(%)	n	(%)	p
Study site					0.43					0.40
Navrongo	220	(35.7)	280	(32.4)		220	(35.5)	280	(32.2)	
Kintampo	198	(32.1)	288	(33.4)		200	(32.3)	290	(33.3)	

Dodowa	199	(32.3)	295	(34.2)		200	(32.3)	300	(34.5)	
Living in a sub-district with a district hospital					<0.01					<0.01
Yes	70	(11.4)	328	(38.0)		70	(11.3)	340	(39.1)	
No	547	(88.7)	535	(62.0)		550	(88.7)	530	(60.9)	
Age					0.83					0.93
≤19	35	(5.7)	53	(6.1)		92	(14.8)	130	(14.9)	
20-34	452	(73.3)	638	(73.9)		439	(70.8)	621	(71.4)	
35-49	130	(21.1)	172	(19.9)		89	(14.4)	119	(13.7)	
Education					0.77					0.12
Did not complete primary	178	(28.9)	257	(29.8)		145	(23.4)	182	(20.9)	
Completed primary	170	(27.6)	222	(25.7)		196	(31.6)	242	(27.8)	
Completed secondary	209	(33.9)	289	(33.5)		207	(33.4)	326	(37.5)	
Complete tertiary	60	(9.7)	95	(11.0)		72	(11.6)	120	(13.8)	
Marital status					0.12					0.32
Married	415	(67.3)	542	(62.8)		351	(56.6)	470	(54.0)	
Cohabitating	150	(24.3)	224	(26.0)		163	(26.3)	260	(29.9)	
Other	52	(8.4)	97	(11.2)		106	(17.1)	140	(16.1)	
Parity					0.37					0.09
Primipara	128	(20.8)	196	(22.7)		187	(30.2)	299	(34.4)	
Multipara	489	(79.3)	667	(77.3)		433	(69.8)	571	(65.6)	
Religion					<0.01					<0.01
Christian	524	(84.9)	656	(76.0)		533	(86.0)	682	(78.4)	
Muslim	51	(8.3)	150	(17.4)		65	(10.5)	145	(16.7)	
Others	42	(6.8)	57	(6.6)		22	(3.6)	43	(4.9)	
Wealth quintiles					<0.01					<0.01
Lowest	144	(23.3)	156	(18.1)		171	(27.6)	188	(21.6)	
Lower	141	(22.9)	155	(18.0)		132	(21.3)	112	(12.9)	
Middle	104	(16.9)	196	(22.7)		118	(19.0)	174	(20.0)	
Higher	120	(19.5)	169	(19.6)		106	(17.1)	192	(22.1)	
Highest	108	(17.5)	187	(21.7)		93	(15.0)	204	(23.5)	
National health insurance					0.21					0.06
Covered	344	(55.8)	510	(59.1)		407	(65.7)	611	(70.2)	
Not covered	272	(44.2)	353	(40.9)		213	(34.4)	259	(29.8)	

p, p-value for chi-squared test.

Table 3 shows the contents of care received by the women and their newborns during ANC, PPC, and PNC. After the intervention, 12.6% of women in the intervention group received all 6 items during ANC, 33.6% received all 3 items during PPC, and 41.5% of women and their newborns received all 14 items during PNC. The adjusted DiD estimators showed no

significant changes across the three phases: 2.2 (p=0.61) at ANC, 2.3 (p=0.69) at PPC, and 8.1 (p=0.35) at PNC. Among the 4 ANC care items which reception were recorded in the CoC card, blood group testing increased from 49.9% to 79.5% in the intervention group. The reception of other care items in the intervention group remained low even after the intervention: hemoglobin tests (40.9%), intermittent preventive treatment for malaria (43.7%), and tetanus toxoid vaccination (46.4%). During the peripartum period, only 47.0% in the intervention group of the follow-up survey initiated breastfeeding within the first 30 minutes. During PNC, over 60% of women and their newborns in the intervention group of the follow-up survey received each care item.

Table 3 Content of ANC, PPC, and PNC (n=2,970)

	Baseline		Follow-up					
	Control (n=617) %	Intervention (n=863) %	Control (n=620) %	Intervention (n=870) %	cDiD	p	aDiD	p
ANC								
All 6 care items received	5.7	4.9	10.7	12.6	2.8	0.52	2.2	0.61
Blood group and Rhesus factor test	52.8	49.9	67.9	79.5	-	-	-	-
HIV test	59.0	55.6	79.7	77.6	-	-	-	-
Blood pressure assessment 4 times	55.3	51.5	71.5	72.4	-	-	-	-
Tetanus toxoid vaccination 2 doses	40.8	39.3	55.3	46.4	-	-	-	-
Intermittent preventive treatment for malaria 3 doses	40.4	36.3	44.2	43.7	-	-	-	-
Hemoglobin test 2 times	28.9	26.4	35.8	40.9	-	-	-	-
PPC								
All 3 care items received	24.3	23.8	31.8	33.6	2.3	0.70	2.3	0.69
Dried newborn's body	87.8	90.0	94.2	93.3	-	-	-	-
Skin-to-skin contact	47.8	45.9	58.9	60.7	-	-	-	-
Initiation of breastfeeding ≤30 minutes	44.9	38.9	46.3	47.0	-	-	-	-
PNC								
All 14 care items received	10.2	11.5	31.8	41.5	8.5	0.34	8.1	0.35
Mother								
All 8 maternal care items received	21.2	22.5	35.2	47.7	11.3	0.12	10.9	0.14
Temperature measurement	65.5	65.2	69.4	78.1	-	-	-	-
Blood pressure assessment	50.2	47.3	69.5	76.8	-	-	-	-
Bleeding check	52.7	58.5	69.2	73.3	-	-	-	-
Breastfeeding problem check	46.4	52.4	66.8	72.0	-	-	-	-
Vitamin A supplement	59.0	57.7	58.9	68.4	-	-	-	-
Fundal height measurement	49.6	51.3	55.0	64.3	-	-	-	-
Perineum/lochia check	47.5	53.4	57.6	63.2	-	-	-	-
Hemoglobin assessment	48.5	48.9	51.1	61.7	-	-	-	-
Newborns								
All 6 newborn care items received	13.1	20.3	52.6	58.2	-1.6	0.87	-2.1	0.82
General physical examination	71.8	69.0	74.8	77.9	-	-	-	-
Temperature measurement	16.1	24.8	71.3	76.0	-	-	-	-
Breastfeeding difficulties check	47.5	57.0	71.0	73.8	-	-	-	-
Umbilical cord bleeding check	49.0	57.5	71.5	73.3	-	-	-	-
OPV	66.8	60.1	66.5	68.4	-	-	-	-
BCG immunization	63.4	60.5	60.0	64.3	-	-	-	-

Note: cDiD, crude difference-in-difference estimators; p, p-values for DiD estimators; aDiD, adjusted difference-in-difference estimators. The DiD estimates were adjusted for study site, living in a sub-district with district hospital, age, education level, marital status, parity, religion, wealth quintiles, and the status of the national health insurance membership.

Table 4 shows the effect of the intervention on adequate contacts with high-quality care. For the per-protocol analysis, we excluded 238 women in the intervention group who did not receive a CoC card and 134 women in the control group who received a CoC card. During ANC, 12.6% of women in the intervention group in the follow-up survey had adequate contacts with high-quality care. The adjusted DiD estimators for adequate contacts with high-quality care during ANC were 2.2 (p=0.61) in the intention-to-treat design, and 2.8 (p=0.54) in the per-protocol design. During PPC, 31.5% of women in the intervention group in the follow-up survey had adequate contacts with high-quality care. The adjusted DiD estimators for adequate contact with high-quality care during PPC were 1.9 (p=0.73) in the intention-to-treat design and 2.7 (p=0.66) in the per-protocol design. During PNC, 33.7% of women in the intervention group in the follow-up survey had adequate contacts with high-quality care. The adjusted DiD estimators for adequate contact with high-quality care during PNC were 12.3 (p=0.13) in the intention-to-treat design and 18.1 (p=0.02) in the per-protocol design. Additionally, Table 4 shows the gap between adequate contacts (i.e., adequate contacts with high- or low-quality care) and quality-adjusted adequate contacts (i.e., adequate contacts with high-quality care). In the intention-to-treat design, 76.9% of women in the intervention group in the follow-up survey had adequate contacts during ANC; however, only 12.6% had quality-adjusted adequate contacts. Moreover, 82.0% delivered with the assistance of a skilled birth attendant at a healthcare facility, while only 31.5% had a skilled delivery with high-quality care. During PNC, 62.2% of women had adequate contacts. However, only 33.7% had quality-adjusted adequate contacts.

Table 4 Effect of intervention on having adequate contacts with high-quality care (n=2,970)

	Baseline		Follow-up: Intention-to-treat						Follow-up: Per-protocol					
	Control (n=617) %	Intervention (n=863) %	Control (n=620) %	Intervention (n=870) %	cDiD	p	aDiD	p	Control (n=486) %	Intervention (n=632) %	cDiD	p	aDiD	p
ANC														
Inadequate contacts	32.7	31.6	22.7	23.1	-	-	-	-	23.7	22.0	-	-	-	-
Adequate contacts with low-quality care	61.6	63.5	66.6	64.3	-	-	-	-	66.5	65.0	-	-	-	-
Adequate contacts with high-quality care	5.7	4.9	10.7	12.6	2.8	0.52	2.2	0.61	9.9	13.0	3.9	0.43	2.8	0.54
PPC														
Inadequate contact	25.0	26.8	20.0	18.1	-	-	-	-	22.6	15.2	-	-	-	-
Adequate contact with low-quality care	54.1	53.1	49.8	50.5	-	-	-	-	50.0	50.6	-	-	-	-
Adequate contact with high-quality care	20.9	20.2	30.2	31.5	2.1	0.72	1.9	0.73	27.4	34.2	7.6	0.25	2.7	0.66
PNC														
Inadequate contacts	87.2	86.8	45.3	37.8	-	-	-	-	48.2	32.1	-	-	-	-
Adequate contacts with low-quality care	9.9	11.9	32.1	28.5	-	-	-	-	32.9	29.8	-	-	-	-
Adequate contacts with high-quality care	2.9	1.3	22.6	33.7	12.7	0.14	12.3	0.13	18.9	38.1	20.8	0.01	18.1	0.02

Note: cDiD, crude difference-in-difference estimators; p, p-values for DiD estimators; aDiD, adjusted difference-in-difference estimators

The DiD estimates were adjusted for study site, living in a sub-district with a district hospital, age, education level, marital status, parity, religion, wealth quintiles, and the status of the national health insurance membership.

Table 5 shows variations in having adequate contacts with high-quality care according to the characteristics of women in the intervention group in the follow-up survey (n=870). Women living in Navrongo were more likely to have adequate contacts with high-quality care during PPC and PNC than women living in Kintampo (AOR=0.27; 95% CI 0.12 to 0.63 at PPC, AOR=0.08; 95% CI 0.03 to 0.19 at PNC) and in Dodowa (AOR=0.20; 95% CI 0.10 to 0.41 at PPC; AOR=0.39; 95% CI 0.23 to 0.65 at PNC). During ANC, however, women living in Dodowa were more likely to have adequate contacts with high-quality care (AOR=3.26; 95% CI 1.67 to 6.33) than those living in Navrongo. Women with national health insurance membership were more likely to have adequate contacts with high-quality care during ANC (AOR=1.78; 95% CI 1.14 to 2.77) and PNC (AOR=1.46; 95% CI 1.07 to 2.00) than those without membership. During ANC, unmarried women or women without cohabiting partners (i.e., single, divorced, separated or widowed) were less likely to have adequate contact with high-quality care (AOR=0.40; 95%CI 0.17 to 0.94), whereas multiparous women were more likely to have adequate contacts with high-quality care than primiparous women (AOR=1.76, 95% CI 1.07 to 2.87). During PPC, women in the lower group in the wealth quintiles were more likely to have adequate contacts with high-quality care, compared with women in the lowest group in the wealth quintiles (AOR=1.80; 95% CI 1.14 to 2.83). During PNC, teenage women were less likely to have adequate contacts with high-quality care than women aged 20 to 34 years (AOR=0.48, 95%CI 0.24-0.95). Women who had completed secondary school were less likely to have adequate contact with high-quality care compared to women who had never completed primary school (AOR=0.64; 95%CI 0.44-0.93).

Table 5 Factors associated with adequate contacts with high-quality care in the intervention group of the follow-up survey (n=870)

	ANC		PPC		PNC	
	AOR	(95%CI)	AOR	(95%CI)	AOR	(95%CI)
Study site						
Navrongo	1.00		1.00		1.00	
Kintampo	0.80	(0.41-1.57)	0.27	(0.12-0.63)	0.08	(0.03-0.19)
Dodowa	3.26	(1.67-6.33)	0.20	(0.10-0.41)	0.39	(0.23-0.65)
Living in a sub-district with a district hospital						
Yes	1.44	(0.83-2.50)	1.57	(0.84-2.91)	1.11	(0.69-1.79)
No	1.00		1.00			
Age						
≤19	0.81	(0.28-2.35)	0.75	(0.39-1.42)	0.48	(0.24-0.95)
20-34	1.00		1.00		1.00	
35-49	0.69	(0.46-1.03)	1.00	(0.65-1.54)	0.79	(0.46-1.37)
Education						
Did not complete primary	1.00		1.00		1.00	
Completed primary	1.09	(0.55-2.18)	1.26	(0.76-2.08)	0.73	(0.50-1.06)
Completed secondary	1.65	(0.76-3.56)	1.18	(0.71-1.98)	0.64	(0.44-0.93)
Complete tertiary	2.32	(0.81-6.67)	0.96	(0.47-1.99)	0.77	(0.37-1.59)
Marital status						
Married	1.00		1.00		1.00	
Cohabitating	0.85	(0.55-1.29)	0.78	(0.51-1.20)	1.03	(0.58-1.82)
Other	0.40	(0.17-0.94)	1.26	(0.84-1.89)	1.14	(0.61-2.12)
Parity						
Primipara	1.00		1.00		1.00	
Multipara	1.76	(1.07-2.87)	1.21	(0.79-1.86)	0.75	(0.41-1.39)
Religion						
Christian	1.00		1.00		1.00	
Muslim	1.11	(0.59-2.08)	0.68	(0.39-1.19)	0.86	(0.47-1.58)
Other	0.50	(0.06-3.91)	1.63	(0.92-2.90)	1.87	(0.83-4.25)
Wealth index						
Lowest	1.00		1.00		1.00	
Lower	0.62	(0.23-1.69)	1.80	(1.14-2.83)	1.19	(0.80-1.76)
Middle	0.70	(0.27-1.80)	1.41	(0.83-2.42)	0.89	(0.53-1.48)
Higher	1.59	(0.68-3.75)	1.48	(0.85-2.60)	1.21	(0.68-2.15)
Highest	1.40	(0.61-3.21)	1.28	(0.70-2.33)	1.98	(1.00-3.92)
National Health Insurance						

Covered	1.78	(1.14-2.77)	1.20	(0.79-1.81)	1.46	(1.07-2.00)
Not covered	1.00		1.00		1.00	

Note: AOR, adjusted odds ratios by multivariable logistic regression analyses with cluster robust standard errors

DISCUSSION

A 12-month implementation of the intervention showed significant effects on high-quality care during regular contacts with healthcare providers at PNC in the per-protocol design. In the intention-to-treat design, however, the intervention showed no significant effects during ANC, PPC, and PNC. In addition, a large gap remained between the crude adequate contacts and quality-adjusted adequate contacts. Hence, despite strengthening regular contacts with healthcare providers through the intervention, women and their newborns did not receive high-quality care. Furthermore, a chance to have adequate contacts and receive high-quality care varied among women with different socio-demographic backgrounds (i.e. study site, and membership of national health insurance) in the intervention group.

The results showed the intervention was efficacious in increasing postnatal contacts and receiving high-quality care among those who actually received the intervention, but did not provide evidence of the effectiveness. Before implementing the intervention, we found that the women were not aware of the importance of PNC, and they believed in a local custom that women and their newborns should stay at home for 6 weeks postpartum. As other intervention studies focused,[31, 32] this intervention was designed to improve women's care seeking behavior and healthcare' provider's knowledge. Using the CoC card, women learned the importance and timings of PNC during ANC, and were given specific appointments for PNC visits. Healthcare providers received a three-day training course and a monthly supervision from the district health management team. The result indicates that the intervention was efficacious, but did not reach all women equally.

The intervention showed no significant effect on ANC. Only 12.6% of women in the intervention group had adequate contacts and received high-quality care. Low coverage of hemoglobin assessment, tetanus toxoid vaccination, and intermittent preventive treatment for malaria could result in low-quality care during ANC. During the intervention, we addressed these challenges by tracking the reception of these care items and blood group test using the CoC card. After the intervention, blood group testing significantly increased, whereas other care items did not change significantly. One possible explanation was that pregnant women could not receive those care items multiple times according to the national guidelines. The percentage of women who had adequate contacts with high-quality care during ANC was higher in Dodowa (23.7%) than in Navrongo (9.3%) and Kintampo (4.5%). A potential explanation is that Dodowa had better governance and was able to procure the essential drugs and equipment for ANC without facing stock-outs as Dodowa is a part of the Greater Accra region.

During PPC, the intervention did not show significant effect of the intervention on adequate contact with high-quality care. Although over 80% of women had adequate contact (i.e. facility-based skilled delivery) in the intervention group during the follow-up survey, only 60% of the women had skin-to-skin contact, and 47% initiated breastfeeding within 30 minutes after delivery. Poor practice of these basic newborn care might result in a large gap between adequate contact and quality-adjusted contact in PPC. These newborn care do not require any equipment or technical skills and should be practiced at any PPC settings even in the absence of midwives.

Women living in Navrongo were more likely to have adequate contacts with healthcare providers and receive high-quality care during PPC and PNC than those living in Kintampo and Dodowa. This implies that the intervention package works effectively through the advanced primary health systems in Navrongo. In Ghana, CHPS initiatives developed a community-based primary health system.[19] The initiatives was first introduced in Navrongo in 1994, and scaled-up

across the country.[19] However, the community-based health systems remain underdeveloped in most parts of the country, including Dodowa and Kintampo. Unequal assignment of midwives among the 3 study sites was a typical example, which could affect the availability and quality of maternal and newborn care. The intervention package could work more effectively in improved health systems.

Women covered by the national health insurance were more likely to have adequate contacts and receive high-quality care during ANC and PNC, whereas unmarried women, women without cohabiting partners, or teenage women were less likely to have adequate contacts with high-quality care during ANC or PNC. This highlights the importance of the national health insurance for women with low socio-economic status to receive essential care. However, only 63% of the women in this study had insurance membership. The evidence presented in this study would be useful in advocating for the enrollment of more pregnant women in the national health insurance scheme.

Limitations

This study has several limitations. First, the clusters in the study were not homogeneous and cluster allocation was uneven. This might have impacted the effects of the intervention. The implementation in the intention-to-treat design allowed women to choose and utilize any healthcare facilities across the clusters, which could also influence the effect of the intervention. Second, the study sites had been exposed to various research projects.[33-36] The effects of our intervention could be built on the effects of previous projects. Third, no standardized measurements for the quality of ANC, PPC, and PNC are available. Each quality of care index consists of different number of items. Moreover, although the value of each item was not equal, we treated all items with an equal weight. Thus, comparing the quality of care among ANC, PPC, and PNC would not be appropriate.

CONCLUSION

The intervention package for strengthening the continuum of care showed a significant effect on contacts with healthcare providers and the quality of care in PNC, but not in ANC and PPC. Women and their newborns did not receive high-quality care during the regular contacts with healthcare providers. The intervention package could work more effectively under a well-developed community-based health systems and with broader national health insurance coverage. Ensuring regular contacts with healthcare providers and improving quality of care are both vital in promoting maternal and newborn health in Ghana.

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Competing interests

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Authors' contribution

SO, MG, AS, KK, FY, CT, SA, KN, ARO, SOA, EA, GQA, JY, AH, and MJ conceived and designed the study. SO, MG, FY, CT, SA, ARO, and SOA conducted interventions and collected data. SO analyzed, interpreted the data, and drafted manuscript. SO, HHL, AS, KK, EA, AH, and

MJ interpreted data. SO, MG, HHL, AS and MJ contributed to the revision of manuscript. AH and MJ are the study guarantor. All authors approved the final version of the manuscript.

Patient consent

The study was approved by the Ethics Review Committee of Ghana Health Service, the Institutional Review Boards of Dodowa HRC and Navrongo HRC, the Institutional Ethics Committee of Kintampo HRC in Ghana, and the Research Ethics Committee of the University of Tokyo in Japan. At the enrolment of the baseline and follow-up surveys, we obtained written informed consent from the women. If the women were under the age of 18, we requested permission from their guardians and obtained their signature on the consent form. At the study enrolment, we obtained oral informed consent from the women to receive the interventions. The study protocol was registered in the ISRCTN Registry (90618993).

Data sharing

The datasets used and/or analyzed during the current study are available on reasonable request from the corresponding author (MJ) under permission by all relevant ethics committees.

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Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	3-4
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	5-6
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	6
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	6-7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		N.A
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	7-9
	4b	Settings and locations where the data were collected		6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	9-10

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		6
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines		NA
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	7,8
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	7,8
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete	7,8

			enumeration, random sampling)	
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	14
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		7,9
	11b	If relevant, description of the similarity of interventions		NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	12-13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		13
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	14
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	14
Recruitment	14a	Dates defining the periods of recruitment and follow-up		8
	14b	Why the trial ended or was stopped		8
Baseline data	15	A table showing baseline demographic and clinical	Baseline characteristics for the individual and cluster levels as	14-15

		characteristics for each group	applicable for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	14, 17-21
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	15-19
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		20-22
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		8
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		24
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	22-24
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		22-24
Other information				
Registration	23	Registration number and		4,6

		name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	Kikuchi K, Ansah E, Okawa S, et al. Ghana's Ensure Mothers and Babies Regular Access to Care (EMBRACE) program: study protocol for a cluster randomized controlled trial. Trials 2015;16:22.
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	25

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts[1,2] to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	**Identification of study as cluster randomised**
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	**Eligibility criteria for clusters**
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	**Whether objective or hypothesis pertains to the cluster level, the individual participant level or both**
Outcome	Clearly defined primary outcome for this report	**Whether the primary outcome pertains to the cluster level, the individual participant level or both**
Randomization	How participants were allocated to interventions	**How clusters were allocated to interventions**
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	**Number of clusters randomized to each group**
Recruitment	Trial status[1]	
Numbers analysed	Number of participants analysed in each group	**Number of clusters analysed in each group**
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	**Results at the cluster or individual participant level as applicable for each primary outcome**
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

[1] Relevant to Conference Abstracts

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