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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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5 **Effect of continuum-of-care intervention package on improving contacts and**
6 **quality of maternal and newborn health care in Ghana: a cluster randomized**
7 **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.

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5 **Conclusions:** The interventions increased contacts with health-care providers and quality of
6 care during PNC. However, a large gap remains between contacts and quality-adjusted contacts.
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8 Maternal and newborn care in Ghana needs to improve its continuity and quality.
9

10 **Trial registration number:** (90618993)
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15 **Strengths and Limitations**

- 16
17 • This was a cluster randomized controlled trial conducted in three rural sites which had
18 diverse ecological characteristics and operated the Health and Demographic Surveillance
19 System.
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23 • This study assessed the effect of intervention on the process dimension of quality-of-care in
24 antenatal, peripartum, and postnatal care accordingly, although the measurements were not
25 standardized.
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29 • The study results could be affected by uneven cluster allocation and the implementation in
30 intention-to-treat design.
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34 • However, our analysis showed that regular contacts with health-care providers did not
35 guarantee quality of care, which suggests that maternal and newborn care program needs to
36 improve continuity and quality of care.
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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

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5 and national health insurance scheme in 2004.²⁰ However, maternal and newborn health remains
6
7 a high-priority challenge, and further effort is needed to strengthen the continuum of care and
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9 improve the quality of care under the implementation of these policies.

10
11 Ghana's Ensure Mothers and Babies Regular Access to Care (EMBRACE)
12
13 implementation research aimed to strengthen CoC.²¹ The major activities included the
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15 development and implementation of an intervention package and evaluation of its effect on CoC.
16
17 Based on the findings of formative research,⁴ we developed an intervention package to ensure
18
19 CoC with health-care providers during ANC, peripartum care (PPC), and PNC. Although CoC
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21 is the primary outcome for the impact evaluation,²² quality of care during the regular contacts is
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23 another important outcome for the process evaluation, which provides multifaceted implications
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25 for maternal and newborn health program. Therefore, this study aimed to examine the effect of
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27 an intervention package on both contacts with health-care providers and quality of care, to
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29 identify the gaps between adequate contacts and quality-adjusted adequate contacts, and to
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31 determine the factors associated with having adequate contacts with high-quality care among
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33 women in the intervention group.

34 35 **METHODS**

36 37 **Study design and setting**

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39 This was a cluster randomized controlled trial using the effectiveness-implementation hybrid
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41 design registered in ISRCTN (90618993).²² We targeted 3 rural sites in Ghana: Navrongo
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43 (northern), Kintampo (central), and Dodowa (southern). Ghana Health Service had Health
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45 Research Centers (HRCs) in the 3 sites, and these HRCs operated the Health and Demographic
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47 Surveillance System.
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50 Each site covered 2 districts and consisted of 36 sub-districts. We included 32 sub-
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52 districts in this study (Navrongo, 12; Kintampo, 12; and Dodowa, 8) and excluded 4 sub-
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54 districts because of other projects implemented or planned during our intervention period. We
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5 used sub-district as a cluster unit as it was the primary unit of the health system. In the pre-
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7 intervention facility assessment, the percentage of health-care facilities with at least one
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9 midwife was 47% in Navrongo, 36% in Dodowa, and 21% in Kintampo.

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11 We created 16 pairs from the 32 clusters, taking into account the population, the volume
12
13 of delivery, and the number of midwife per cluster. A data analyst who was not a member of the
14
15 study team randomly allocated the paired clusters using computer-generated random sequences.
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17 However, we assigned 3 sub-districts with a district hospital to the intervention group as
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19 majority of the childbirths took place in the hospitals. We informed about the implementation of
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21 the intervention to the community people and health-care providers in the intervention group
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23 only. However, complete blinding was not feasible; we implemented the intervention in the
24
25 intention-to-treat design, which did not control for women's choice and access to health-care
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27 facilities across a cluster boundary.

28 29 **Participants and intervention**

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

34
35 We implemented the intervention for 12 months (October 1, 2014 to September 30,
36
37 2015). The details of the intervention were described previously.²² Women were enrolled to the
38
39 intervention when they had contacts with health-care providers anytime from pregnancy to the
40
41 postpartum period.

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

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9 We emphasized to implement the intervention using the existing health system and
10 resource; all intervention facilities in the 3 sites had re-orientation of health-care providers, and
11 implemented all or a part of the intervention package depending on availability of resource and
12 infrastructure. In addition, district health management teams conducted monthly supervision in
13 health-care facilities, monitored the performance of the interventions, and had a monthly
14 meeting to report the progress and discuss the challenges in collaboration with research teams.
15
16 In the control group, women and their newborns received the standard care.

22 23 **Survey**

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

33
34 For the first stage, we defined sub-districts as a cluster unit. A sub-district is composed
35 of several administrative community units. We used the administrative community units as a
36 primary sampling unit, and randomly selected primary sampling units from each sub-districts
37 that corresponds to the probability proportionate to the population. For the second stage, we
38 randomly selected 10 women per primary sampling unit.

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40 Trained research assistants performed the survey by visiting the households of the
41 eligible women and conducting face-to-face interviews with women who had no knowledge
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5 about the cluster allocation. The structured questionnaire included women's socio-demographic
6 characteristics; frequency and timing of contacts with health-care providers; contents of care
7 that women and their newborn received during ANC, PPC, and PNC; and whether they received
8 the CoC card. The frequency and timing of contacts and contents of care corresponded to the
9 recommendation of the Ghana National Safe Motherhood Service Protocol.²³
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14 15 **Main outcome measures**

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17 We defined adequate contacts based on the frequency and timing of contacts with
18 health-care providers as follows: at least 4 contacts with health-care providers during pregnancy,
19 delivery with assistance of skilled health-care providers at a health-care facility, and 3 contacts
20 with health-care providers within 48 hours, at 1 week (3-10 days), and at 6 weeks (36-48 days)
21 postpartum (Table 1).
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26
27 We measured the quality of care based on the contents of care received by the women
28 and their newborns during ANC, PPC, and PNC (Table 1). The process-of-care dimension in
29 Donabedian's framework was employed.⁷ We created quality of care indexes that consisted of 6
30 care items for ANC, 3 for PPC, and 14 for PNC. High-quality care was defined as receiving all
31 care items during ANC, PPC, and PNC.
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37 Having adequate contacts with health-care providers and high-quality care was
38 considered the primary outcome, and the variable was composed of 3 categories: inadequate
39 contacts regardless of care quality, adequate contacts with low-quality care, and adequate
40 contacts with high-quality care. (i.e., quality-adjusted adequate contacts).
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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

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

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

22 23 **Ethical approval**

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

36 37 38 **RESULTS**

39
40 We analyzed the baseline survey data of 1,480 women and the follow-up survey data of 1,490
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42 women. In the baseline survey, 617 (41.7%) were sampled from the control group, and 863
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44 (58.3%) were sampled from the intervention group. In the follow-up survey, 620 (41.6%) were
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46 sampled from the control group, and 870 (58.4%) were sampled from the intervention group. In
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48 addition, we excluded the data of 10 women in one primary sampling unit from the baseline and
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50 follow-up survey datasets accordingly, because it did not have 10 eligible women during the
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52 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)				<i>p</i>	Follow-up (n=1,490)				<i>p</i>
	Control (n=617)		Intervention (n=863)			Control (n=620)		Intervention (n=870)		
	n	(%)	n	(%)		n	(%)	n	(%)	
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
Cohabiting	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				DiD [†]	<i>p</i>
	Control (n=617)		Intervention (n=863)		Control (n=620)		Intervention (n=870)			
	n	(%)	n	(%)	n	(%)	n	(%)		
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)				DiD	<i>p</i>				
	Control (n=617)		Intervention n=863		Control (n=620)		Intervention (n=870)		Control (n=486)				Intervention (n=632)			
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)			n	(%)		
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

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

13
14 The intervention showed no significant effect on ANC. Only 12.6% of women in the
15 intervention group had adequate contacts and received high-quality care. Low coverage of
16 hemoglobin assessment, tetanus toxoid vaccination, and intermittent preventive treatment for
17 malaria could result in low-quality care during ANC. During the intervention, we addressed these
18 challenges by tracking the use of these care items and blood group test using the CoC card. After
19 the intervention, blood group test significantly increased, whereas other care items did not change
20 significantly. One possible explanation was that pregnant women were required to receive those
21 care items multiple times. The percentage of women who had adequate contacts with high-quality
22 care during ANC was higher in Dodowa (23.7%) than in Navrongo (9.3%) and Kintampo (4.5%). A
23 potential explanation is that Dodowa has geographical advantages in procuring or accessing
24 essential medicines and equipment for ANC as it is a part of Greater Accra region.

25
26 Women living in Navrongo were more likely to have adequate contacts with health-care
27 providers and receive high-quality care during PPC and PNC than those living in Kintampo and
28 Dodowa, which suggests that the intervention package works effectively through the advanced
29 primary health-care system in Navrongo. In Ghana, CHPS initiatives developed a community-based
30 primary health-care system.¹⁹ The initiatives was first introduced in Navrongo in 1994, and scaled-

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5 up across the country.¹⁹ However, the health system remains underdeveloped in most parts of the
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7 country, including Dodowa and Kintampo. Unequal assignment of midwives among the 3 study
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9 sites is a typical example, which could affect the availability and quality of maternal and newborn
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11 care. The intervention package could work more effectively in an improved health system.
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14 Women covered by the national health insurance were more likely to have adequate
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16 contacts and receive high-quality care during ANC and PNC, whereas women in the lowest wealth
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18 group were less likely to have adequate contacts with high-quality care during ANC and PNC
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20 compared with women in the highest wealth group. This highlights the importance of the national
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22 health insurance. Women with insurance membership could benefit from a free package of ANC,
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24 delivery, and PNC services with an annual premium of 12 Ghana Cedi (or around 2.7 USD).²⁷
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26 However, only 63% of the women in this study had insurance membership. The evidence presented
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28 in this study would be useful in advocating for the enrollment of more women in the national health
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30 insurance scheme.
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35 **Limitations**

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

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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

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

11 The study was approved by the Ethics Review Committee of Ghana Health Service, the Institutional
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13 Kintampo HRC in Ghana, and the Research Ethics Committee of the University of Tokyo in Japan.
14
15 At the enrolment of the baseline and follow-up surveys, we obtained written informed consent from
16 the women. If the women were under the age of 18, we requested permission from their guardians
17 and obtained their signature on the consent form. At the study enrolment, we obtained oral informed
18 consent from the women to receive the interventions. The study protocol was registered in the
19 ISRCTN Registry (90618993).
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30 **Data sharing**

31 The datasets used and/or analyzed during the current study are available on reasonable request from
32 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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1 **Effect of continuum-of-care intervention package on improving contacts and**
2 **quality of maternal and newborn health care in Ghana: a cluster randomized**
3 **controlled trial**

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32 ABSTRACT

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

36 **Design:** Cluster randomized controlled trial.

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

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

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

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

49 **Results:** The difference-in-difference method was used to assess the effects of the intervention
50 on the study outcome. The percentage of adequate contacts with high-quality care in the
51 intervention group in the follow-up survey and the adjusted difference-in-difference estimators
52 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
53 ($p=0.13$) at PNC in the intention-to-treat design, whereas 13.0% and 2.8 ($p=0.54$) at ANC,
54 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
55 that assigned the study sample by possession of the continuum-of-care card.

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5 56 **Conclusions:** The interventions improved contacts with healthcare providers and quality of care
6
7 57 during PNC. However, having adequate contact did not guarantee high-quality care. Maternal
8
9 58 and newborn care in Ghana needs to improve its continuity and quality.

10
11 59 **Trial registration number:** (90618993)
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61 **Strengths and Limitations**

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18 62 • This was a cluster randomized controlled trial conducted in three rural sites which had
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20 63 diverse socio-economic and ecological backgrounds and operated the Health and
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22 64 Demographic Surveillance System.
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24 65 • This study assessed the effect of the intervention on having adequate contact of women and
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26 66 their newborns with healthcare providers and their reception of high-quality care in
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28 67 antenatal, peripartum, and postnatal care.
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30 68 • The results showed that regular contacts with healthcare providers did not guarantee quality
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32 69 of care, although the results could be affected by uneven cluster allocation and
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34 70 contamination.
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36 71 • Maternal and newborn care program needs to improve continuity and quality of care in
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38 72 Ghana.
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74 INTRODUCTION

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

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

96 Ghana is one of the sub-Saharan African countries with an estimated maternal mortality
97 ratio of 380/100,000 live births in 2013.[17] Neonatal mortality rate was 29/1,000 live births in
98 2010-2014, with a minor reduction in the last decade.[18] The government of Ghana introduced
99 health policies to mitigate the financial and geographical constraints affecting the access to

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5 100 healthcare services: community-based health planning and services (CHPS) initiative in
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7 101 1999,[19] and national health insurance scheme in 2004.[20] In this scheme, pregnant women
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9 102 are able to obtain their health insurance which includes a free package of ANC, delivery,
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11 103 caesarean section, and PNC services without paying the annual premium and processing
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13 104 fees.[21, 22] Our previous studies showed that women with national health insurance were more
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15 105 likely to have four ANC visits and deliver at a healthcare facility.[23, 24] Despite improvements
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17 106 in coverage for maternal and child health, further effort is needed to strengthen the CoC and
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19 107 improve the quality of care under the implementation of these policies.

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22 108 Ghana's Ensure Mothers and Babies Regular Access to Care (EMBRACE)
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24 109 implementation research aimed to strengthen CoC.[25] The major activities included the
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26 110 development and implementation of an intervention package and evaluation of its effect on
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28 111 CoC. Based on the findings of formative research,[4] we developed an intervention package to
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30 112 ensure CoC with healthcare providers during ANC, peripartum care (PPC), and PNC. Although
31
32 113 CoC is the primary outcome for the impact evaluation,[26] quality of care during the regular
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34 114 contacts is another important outcome for the process evaluation, which provides multifaceted
35
36 115 implications for maternal and newborn health program. Therefore, the objectives of this study
37
38 116 were to examine the effects of the CoC intervention package on having adequate contacts with
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40 117 healthcare providers and high-quality care by the mothers and their newborns compared to the
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42 118 standard maternal and newborn care under the national guidelines, and to determine the factors
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44 119 associated with having adequate contacts with high-quality care among those in the intervention
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46 120 group in the follow-up survey.

47 48 49 50 121 **METHODS**

51 52 122 **Study design and setting**

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54 123 This was a cluster randomized controlled trial using the effectiveness-implementation hybrid
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56 124 design registered in ISRCTN (90618993).[26] In order to enhance the generalizability of study
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5 125 findings in rural setting of Ghana, we selected 3 rural sites: Navrongo (northern), Kintampo
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7 126 (central), and Dodowa (southern) which had diverse socio-economic and ecological background
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9 127 and health systems challenges. Additionally, these study sites had Health Research Centers
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11 128 (HRCs) under the Ghana Health Service, and these HRCs operated the Health and Demographic
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13 129 Surveillance System. Such research infrastructure could be beneficial for the quality control of
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15 130 the intervention and surveys.

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18 131 Each study site covered 2 districts and consisted of 36 sub-districts. We included 32
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20 132 sub-districts in this study (Navrongo, 12; Kintampo, 12; and Dodowa, 8) and excluded 4 sub-
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22 133 districts because of other projects implemented or planned during our intervention period. We
23
24 134 used sub-district as a cluster unit as it was the primary unit of the health system. In the pre-
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26 135 intervention facility assessment, the percentage of healthcare facilities with at least one midwife
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28 136 was 47% in Navrongo, 36% in Dodowa, and 21% in Kintampo.

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31 137 We made 16 pairs of the clusters (Navrongo, 6; Kintampo 6; and Dodowa, 4), taking
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33 138 into account the population, the volume of delivery, and the number of midwives in each
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35 139 cluster. Then, we randomly assigned the clusters within a pair to the intervention or the control
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37 140 groups. A data analyst who was not a member of the study team randomly allocated the paired
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39 141 clusters using computer-generated random sequences. However, we assigned 3 clusters with a
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41 142 district hospital to the intervention group as majority of the childbirths took place in these
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43 143 hospitals. We informed about the implementation of the intervention to the community people
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45 144 and healthcare providers in the intervention group only. However, complete blinding was not
46
47 145 feasible; we implemented the intervention in the intention-to-treat design, which did not control
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49 146 for women's choice and access to healthcare facilities across a cluster boundary.

50 51 52 147 **Participants and intervention**

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54 148 Women who were aged between 15 – 49 years old, and delivered between October 1, 2014 and
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56 149 September 30, 2015 in the intervention group were eligible for study enrolment.[26]
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5 150 We implemented the intervention for 12 months (October 1, 2014 to September 30,
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7 151 2015) as initially planned in the protocol. The details of the intervention were described
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9 152 previously.[26] Women were enrolled to the intervention when they had contacts with
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11 153 healthcare providers anytime from pregnancy to the postpartum period.
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14 154 The intervention package was composed of 4 interventions. First, healthcare providers
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16 155 underwent reorientation about CoC. Second, healthcare providers distributed the CoC card to
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18 156 women, which contains the schedule and actual dates of contacts with healthcare providers,
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20 157 information on essential care and birth preparedness, and the presence of danger signs.
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22 158 Healthcare providers and women utilized the CoC card in every contact. Third, healthcare
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24 159 providers retained women and their newborns in the healthcare facility for the first 24 hours
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26 160 postpartum to provide the first PNC. Fourth, healthcare providers made home visits to provide
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28 161 PNC to women and their newborns within the first 48 hours if they missed the first postnatal
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30 162 contact by 24 hours postpartum.
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33 163 We emphasized to implement the intervention using the existing health systems and
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35 164 resource; all intervention facilities in the 3 sites had re-orientation of healthcare providers, and
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37 165 implemented all or a part of the intervention package depending on availability of resource and
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39 166 infrastructure. In addition, district health management teams conducted monthly supervision in
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41 167 healthcare facilities, monitored the performance of the interventions, and had a monthly meeting
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43 168 to report the progress and discuss the challenges in collaboration with research teams. In the
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45 169 control group, women and their newborns received the standard care recommended by the
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47 170 Ghana National Safe Motherhood Service Protocol.[27] During the trial period, we did not
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49 171 observe any harms or unintended events in the intervention or the control groups.
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51 172 **Survey**

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54 173 We conducted the baseline survey from July to September 2014, with a sample of 1,500 women
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56 174 who delivered between September 1, 2012 and June 30, 2014, and the follow-up survey was
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58 175 performed from October to December 2015, with a sample of 1,500 women who received care
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5 176 during the intervention period. We calculated the required sample size based on an expected
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7 177 increase in antenatal contacts from 86.6 to 95.0% according to the finding of our formative
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9 178 study.[4] We considered a 95% confidence interval, 80% power, an intraclass correlation
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11 179 coefficient of 0.02675, and 10% attrition in the sample size calculation.[26] We performed two-
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13 180 stage random sampling to select 500 eligible women from each study site for the baseline and
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15 181 follow-up surveys.

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18 182 For the first stage, we defined sub-districts as a cluster unit. A sub-district is composed
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20 183 of several administrative community units. We used the administrative community units as a
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22 184 primary sampling unit, and randomly selected primary sampling units from each sub-district
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24 185 that corresponded to the probability proportionate to the population. For the second stage, we
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26 186 randomly selected 10 women per primary sampling unit.

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29 187 Trained research assistants performed the survey by visiting the households of the
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31 188 eligible women and conducting face-to-face interviews with women who had no knowledge
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33 189 about the cluster allocation. The structured questionnaire included women's socio-demographic
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35 190 characteristics; frequency and timing of contacts with healthcare providers; contents of care that
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37 191 women and their newborn received during ANC, PPC, and PNC; and whether they received the
38
39 192 CoC card. The frequency and timing of contacts and contents of care corresponded to the
40
41 193 recommendation of the Ghana National Safe Motherhood Service Protocol.[27]

42 43 194 **Main outcome measures**

44
45 195 We defined adequate contacts based on the frequency and timing of contacts with
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47 196 healthcare providers as follows: at least 4 contacts with healthcare providers during pregnancy,
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49 197 delivery with assistance of skilled healthcare providers at a healthcare facility, and 3 contacts
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51 198 with healthcare providers within 48 hours, at 1 week (3-10 days), and at 6 weeks (36-48 days)
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53 199 postpartum (Table 1).

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56 200 We measured the quality of care based on the contents of care received by the women
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58 201 and their newborns during ANC, PPC, and PNC (Table 1). The process-of-care dimension in
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5 202 Donabedian's framework was employed.[7] We created quality of care indexes that consisted of
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7 203 6 care items for ANC, 3 for PPC, and 14 for PNC. High-quality care was defined as receiving
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9 204 all care items during ANC, PPC, and PNC.

11 205 Having adequate contacts with healthcare providers and high-quality care was
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13 206 considered as the primary study outcome. The variable was composed of 3 categories:
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15 207 inadequate contacts regardless of care quality, adequate contacts with low-quality care, and
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17 208 adequate contacts with high-quality care. (i.e., quality-adjusted adequate contacts).

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210 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

211

212 **Confounders**

213 We considered the following variables as potential confounders: study site, living in a sub-
214 district with a district hospital, age, education, marital status, parity, religion, wealth quintile
215 index, and the status of national health insurance membership. Of these variables, age and parity
216 were initially continuous variables, and converted to categorical variables: age (≤ 19 , 20-34, and
217 $\geq 35-49$), parity (primipara and multipara). The variable of wealth quintile index was generated
218 by performing principal component analysis of 13 household assets.

219 **Statistical analysis**

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

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5 238 with cluster robust estimators of variance, controlling for individual characteristics. Robust
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7 239 estimators of variance is a technique used to estimate cluster robust standard errors and adjust
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9 240 the confidence intervals of the DiD estimators when the regression model is potentially affected
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11 241 by cluster correlations.[29]

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14 242 We also considered the potential effect of contaminations. Therefore, we calculated
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16 243 DiD estimators in the intention-to-treat and per-protocol designs separately. The intention-to-
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18 244 treat design focuses whether the intervention works in the real world setting, which shows
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20 245 effectiveness of the intervention.[30] In the intention-to-treat analysis, we compared the
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22 246 percentages of the study outcomes between the intervention and the control groups
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24 247 corresponded to the initial cluster allocation. The results could be affected by coverage and
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26 248 contamination of the intervention. The per-protocol design focuses whether the intervention
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28 249 works in the ideal setting, which shows the efficacy of the intervention.[30] In the per-protocol
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30 250 analysis, we treated the possession of the CoC card as actual participation in the intervention.
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32 251 Thus, women in the intervention group who did not receive the CoC card and women in the
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34 252 control group who received the CoC card were excluded from the DiD analysis.

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37 253 Finally, we performed sub-group analyses to identify factors associated with having
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39 254 adequate contacts with high-quality care among women in the intervention group in the follow-
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41 255 up survey (n=870). This analysis focused on identifying the characteristics of women who had
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43 256 greater chances of having adequate contacts with high-quality care in the intervention area. We
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45 257 used multivariable logistic regression with cluster robust standard errors. The independent
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47 258 variables were study site, living in a sub-district with a district hospital, age, education, marital
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49 259 status, parity, religion, wealth quintiles, and the status of national health insurance membership.
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51 260 We used Stata 13 (College Station, TX: Stata Corp LP) for the analyses.

52 261 **Participants and Public involvement**

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56 262 Participants and public were not involved in the design of, the recruitment to, and conduct of the
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58 263 study because this was a randomized controlled trial. However, community people in the
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264 intervention group were announced about the EMBRACE project at the commencement of the
265 trial.

266 **Ethical approval**

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

273 **RESULTS**

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

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

283 Table 2 Basic characteristics of women (n=2970)

	Baseline (n=1,480)				p	Follow-up (n=1,490)				p
	Control (n=617)		Intervention (n=863)			Control (n=620)		Intervention (n=870)		
	n	(%)	n	(%)		n	(%)	n	(%)	
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)	
Cohabiting	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)	

284 p, p-value for chi-squared test.

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

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5 289 significant changes across the three phases: 2.2 (p=0.61) at ANC, 2.3 (p=0.69) at PPC, and 8.1
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7 290 (p=0.35) at PNC. Among the 4 ANC care items which reception were recorded in the CoC card,
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9 291 blood group testing increased from 49.9% to 79.5% in the intervention group. The reception of
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11 292 other care items in the intervention group remained low even after the intervention: hemoglobin
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13 293 tests (40.9%), intermittent preventive treatment for malaria (43.7%), and tetanus toxoid
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15 294 vaccination (46.4%). During the peripartum period, only 47.0% in the intervention group of the
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17 295 follow-up survey initiated breastfeeding within the first 30 minutes. During PNC, over 60% of
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19 296 women and their newborns in the intervention group of the follow-up survey received each care
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21 297 item.
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299 Table 3 Content of ANC, PPC, and PNC (n=2,970)

	Baseline		Follow-up		cDiD	p	aDiD	p
	Control (n=617) %	Intervention (n=863) %	Control (n=620) %	Intervention (n=870) %				
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	-	-	-	-

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5 301 Note: cDiD, crude difference-in-difference estimators; p, p-values for DiD estimators; aDiD,
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7 302 adjusted difference-in-difference estimators. The DiD estimates were adjusted for study site,
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9 303 living in a sub-district with district hospital, age, education level, marital status, parity, religion,
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11 304 wealth quintiles, and the status of the national health insurance membership.

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14 305 Table 4 shows the effect of the intervention on adequate contacts with high-quality care.
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16 306 For the per-protocol analysis, we excluded 238 women in the intervention group who did not
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18 307 receive a CoC card and 134 women in the control group who received a CoC card. During
19
20 308 ANC, 12.6% of women in the intervention group in the follow-up survey had adequate contacts
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22 309 with high-quality care. The adjusted DiD estimators for adequate contacts with high-quality care
23
24 310 during ANC were 2.2 ($p=0.61$) in the intention-to-treat design, and 2.8 ($p=0.54$) in the per-
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26 311 protocol design. During PPC, 31.5% of women in the intervention group in the follow-up
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28 312 survey had adequate contacts with high-quality care. The adjusted DiD estimators for adequate
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30 313 contact with high-quality care during PPC were 1.9 ($p=0.73$) in the intention-to-treat design and
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32 314 2.7 ($p=0.66$) in the per-protocol design. During PNC, 33.7% of women in the intervention group
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34 315 in the follow-up survey had adequate contacts with high-quality care. The adjusted DiD
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36 316 estimators for adequate contact with high-quality care during PNC were 12.3 ($p=0.13$) in the
37
38 317 intention-to-treat design and 18.1 ($p=0.02$) in the per-protocol design. Additionally, Table 4
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40 318 shows the gap between adequate contacts (i.e., adequate contacts with high- or low-quality care)
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42 319 and quality-adjusted adequate contacts (i.e., adequate contacts with high-quality care). In the
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44 320 intention-to-treat design, 76.9% of women in the intervention group in the follow-up survey had
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46 321 adequate contacts during ANC; however, only 12.6% had quality-adjusted adequate contacts.
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48 322 Moreover, 82.0% delivered with the assistance of a skilled birth attendant at a healthcare
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50 323 facility, while only 31.5% had a skilled delivery with high-quality care. During PNC, 62.2% of
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52 324 women had adequate contacts. However, only 33.7% had quality-adjusted adequate contacts.
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325 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	Intervention	Control	Intervention	Control	Intervention	Control	Intervention							
	(n=617)	(n=863)	(n=620)	(n=870)	(n=486)	(n=622)	(n=486)	(n=622)							
	%	%	%	%	cDiD	p	aDiD	p	%	%	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	

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

327 The DiD estimates were adjusted for study site, living in a sub-district with a district hospital, age, education level, marital status, parity,

328 religion, wealth quintiles, and the status of the national health insurance membership.

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4 329 Table 5 shows variations in having adequate contacts with high-quality care according to the
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6 330 characteristics of women in the intervention group in the follow-up survey (n=870). Women living
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8 331 in Navrongo were more likely to have adequate contacts with high-quality care during PPC and
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10 332 PNC than women living in Kintampo (AOR=0.27; 95% CI 0.12 to 0.63 at PPC, AOR=0.08; 95% CI
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12 333 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
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14 334 0.23 to 0.65 at PNC). During ANC, however, women living in Dodowa were more likely to have
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16 335 adequate contacts with high-quality care (AOR=3.26; 95% CI 1.67 to 6.33) than those living in
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18 336 Navrongo. Women with national health insurance membership were more likely to have adequate
19
20 337 contacts with high-quality care during ANC (AOR=1.78; 95% CI 1.14 to 2.77) and PNC
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22 338 (AOR=1.46; 95% CI 1.07 to 2.00) than those without membership. During ANC, unmarried women
23
24 339 or women without cohabiting partners (i.e., single, divorced, separated or widowed) were less likely
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26 340 to have adequate contact with high-quality care (AOR=0.40; 95%CI 0.17 to 0.94), whereas
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28 341 multiparous women were more likely to have adequate contacts with high-quality care than
29
30 342 primiparous women (AOR=1.76, 95% CI 1.07 to 2.87). During PPC, women in the lower group in
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32 343 the wealth quintiles were more likely to have adequate contacts with high-quality care, compared
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34 344 with women in the lowest group in the wealth quintiles (AOR=1.80; 95% CI 1.14 to 2.83). During
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36 345 PNC, teenage women were less likely to have adequate contacts with high-quality care than women
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38 346 aged 20 to 34 years (AOR=0.48, 95%CI 0.24-0.95). Women who had completed secondary school
39
40 347 were less likely to have adequate contact with high-quality care compared to women who had never
41
42 348 completed primary school (AOR=0.64; 95%CI 0.44-0.93).

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350 Table 5 Factors associated with adequate contacts with high-quality care in the intervention group
 351 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	
Cohabiting	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	

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

354 DISCUSSION

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

364 The results showed the intervention was efficacious in increasing postnatal contacts and
 365 receiving high-quality care among those who actually received the intervention, but did not provide
 366 evidence of the effectiveness. Before implementing the intervention, we found that the women were
 367 not aware of the importance of PNC, and they believed in a local custom that women and their
 368 newborns should stay at home for 6 weeks postpartum. As other intervention studies focused,[31,
 369 32] this intervention was designed to improve women's care seeking behavior and healthcare'
 370 provider's knowledge. Using the CoC card, women learned the importance and timings of PNC
 371 during ANC, and were given specific appointments for PNC visits. Healthcare providers received a
 372 three-day training course and a monthly supervision from the district health management team. The
 373 result indicates that the intervention was efficacious, but did not reach all women equally.

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4 374 The intervention showed no significant effect on ANC. Only 12.6% of women in the
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6 375 intervention group had adequate contacts and received high-quality care. Low coverage of
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8 376 hemoglobin assessment, tetanus toxoid vaccination, and intermittent preventive treatment for
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10 377 malaria could result in low-quality care during ANC. During the intervention, we addressed these
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12 378 challenges by tracking the reception of these care items and blood group test using the CoC card.
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14 379 After the intervention, blood group testing significantly increased, whereas other care items did not
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16 380 change significantly. One possible explanation was that pregnant women could not receive those
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18 381 care items multiple times according to the national guidelines. The percentage of women who had
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20 382 adequate contacts with high-quality care during ANC was higher in Dodowa (23.7%) than in
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22 383 Navrongo (9.3%) and Kintampo (4.5%). A potential explanation is that Dodowa had better
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24 384 governance and was able to procure the essential drugs and equipment for ANC without facing
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26 385 stock-outs as Dodowa is a part of the Greater Accra region.

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29 386 During PPC, the intervention did not show significant effect of the intervention on adequate
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31 387 contact with high-quality care. Although over 80% of women had adequate contact (i.e. facility-
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33 388 based skilled delivery) in the intervention group during the follow-up survey, only 60% of the
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35 389 women had skin-to-skin contact, and 47% initiated breastfeeding within 30 minutes after delivery.
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37 390 Poor practice of these basic newborn care might result in a large gap between adequate contact and
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39 391 quality-adjusted contact in PPC. These newborn care do not require any equipment or technical
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41 392 skills and should be practiced at any PPC settings even in the absence of midwives.

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44 393 Women living in Navrongo were more likely to have adequate contacts with healthcare
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46 394 providers and receive high-quality care during PPC and PNC than those living in Kintampo and
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48 395 Dodowa. This implies that the intervention package works effectively through the advanced
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50 396 primary health systems in Navrongo. In Ghana, CHPS initiatives developed a community-based
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52 397 primary health system.[19] The initiatives was first introduced in Navrongo in 1994, and scaled-up

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4 398 across the country.[19] However, the community-based health systems remain underdeveloped in
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6 399 most parts of the country, including Dodowa and Kintampo. Unequal assignment of midwives
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8 400 among the 3 study sites was a typical example, which could affect the availability and quality of
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10 401 maternal and newborn care. The intervention package could work more effectively in improved
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12 402 health systems.

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15 403 Women covered by the national health insurance were more likely to have adequate
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17 404 contacts and receive high-quality care during ANC and PNC, whereas unmarried women, women
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19 405 without cohabiting partners, or teenage women were less likely to have adequate contacts with
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21 406 high-quality care during ANC or PNC. This highlights the importance of the national health
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23 407 insurance for women with low socio-economic status to receive essential care. However, only 63%
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25 408 of the women in this study had insurance membership. The evidence presented in this study would
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27 409 be useful in advocating for the enrollment of more pregnant women in the national health insurance
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29 410 scheme.

31 411 **Limitations**

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34 412 This study has several limitations. First, the clusters in the study were not homogeneous and cluster
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36 413 allocation was uneven. This might have impacted the effects of the intervention. The
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38 414 implementation in the intention-to-treat design allowed women to choose and utilize any healthcare
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40 415 facilities across the clusters, which could also influence the effect of the intervention. Second, the
41
42 416 study sites had been exposed to various research projects.[33-36] The effects of our intervention
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44 417 could be built on the effects of previous projects. Third, no standardized measurements for the
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46 418 quality of ANC, PPC, and PNC are available. Each quality of care index consists of different
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48 419 number of items. Moreover, although the value of each item was not equal, we treated all items with
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50 420 an equal weight. Thus, comparing the quality of care among ANC, PPC, and PNC would not be
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52 421 appropriate.

422 **CONCLUSION**

423 The intervention package for strengthening the continuum of care showed a significant effect on
424 contacts with healthcare providers and the quality of care in PNC, but not in ANC and PPC.

425 Women and their newborns did not receive high-quality care during the regular contacts with
426 healthcare providers. The intervention package could work more effectively under a well-developed
427 community-based health systems and with broader national health insurance coverage. Ensuring
428 regular contacts with healthcare providers and improving quality of care are both vital in promoting
429 maternal and newborn health in Ghana.

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435 **Competing interests**

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439 that could appear to have influenced this work.

440 **Authors' contribution**

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

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4 444 MJ interpreted data. SO, MG, HHL, AS and MJ contributed to the revision of manuscript. AH and
5
6 445 MJ are the study guarantor. All authors approved the final version of the manuscript.
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9 446 **Patient consent**

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11 447 The study was approved by the Ethics Review Committee of Ghana Health Service, the Institutional
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13 448 Review Boards of Dodowa HRC and Navrongo HRC, the Institutional Ethics Committee of
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15 449 Kintampo HRC in Ghana, and the Research Ethics Committee of the University of Tokyo in Japan.
16
17 450 At the enrolment of the baseline and follow-up surveys, we obtained written informed consent from
18
19 451 the women. If the women were under the age of 18, we requested permission from their guardians
20
21 452 and obtained their signature on the consent form. At the study enrolment, we obtained oral informed
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23 453 consent from the women to receive the interventions. The study protocol was registered in the
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25 454 ISRCTN Registry (90618993).
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29 455 **Data sharing**

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31 456 The datasets used and/or analyzed during the current study are available on reasonable request from
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33 457 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 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

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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. <i>Trials</i> 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

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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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