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2 **Abstract**

3 **Purpose:** Intermittent preventive treatment with sulphadoxine-pyrimethamine for pregnant women
4 (IPTp-SP) coverage remains far below the desirable goal of at least 3 doses before delivery. This
5 study evaluates an innovative intervention using mobile phones as a means to increase the coverage
6 of the third dose of IPTp-SP.

7 **Methods:** This study was designed as an open-label pragmatic, two-arm, randomised trial conducted
8 in Burkina Faso. Pregnant women who attended antenatal clinic (ANC) visits were included at their
9 first ANC visit and followed until delivery. The intervention consisted of mobile phones used to track
10 directly pregnant women.

11 **Results:** In total, 248 pregnant women were included in the study. The proportion of women who
12 received at least three doses of IPTp-SP was 54.6%. In the intervention group, 54.1% of women
13 received at least three doses of IPTp-SP versus 55.1% in the control group, but the difference was not
14 significant (adjusted odds ratio “aOR”, 0.86; 95% confidence interval “95% CI”, 0.49-1.51). Women
15 in the intervention group were likely to timely attend to their ANC visits than women in the control
16 group (aOR, 3.21; 95% CI, 1.91-5.39).

17 **Conclusions:** Mobile phones intervention did not increase the proportion of women receiving 3 doses
18 of IPTp-SP; however, it may contribute to improve the rate of timely attendance to ANC visits.

19 **Trial registration:** PACTR202106905150440

20 **Keywords:** Mobile phones, Intermittent Preventive Treatment of malaria, Sulfadoxine-
21 Pyrimethamine, Antenatal care, Burkina Faso.

22

23 **List of abbreviations and acronyms**

24 ANC: Antenatal clinic

25 CI: Confidence interval

26 CRF: Case report form

27 IPTp: Intermittent preventive treatment in pregnancy

28 ITN: Insecticide-treated bed-nets

29 mHealth: Mobile health

30 OR: Odd ratio

31 SD: Standard deviation

32 SP: Sulfadoxine-pyrimethamine

33 SSA: sub-Saharan Africa

34 WHO: World Health Organisation

35 **Introduction**

36 In sub-Saharan Africa (SSA), over 30 million pregnant women are at risk of malaria infection each
37 year [1]. Pregnant women are particularly vulnerable to malaria infection, resulting in negative
38 consequences for the health of the mother and the new-born, mainly maternal anaemia, and low
39 birthweight, and increasing maternal and infant mortality and morbidity [2].

40 For malaria control in pregnancy, the World Health Organisation (WHO) recommends the use of
41 insecticide-treated bed-nets (ITNs), intermittent preventive treatment with sulfadoxine-
42 pyrimethamine (IPTp-SP) and prompt and effective management of clinical cases [3]. IPTp-SP is a
43 key intervention and highly cost-effective in preventing the harmful consequences of malaria on
44 maternal and foetal outcomes [4]. The administration of SP consisted of at least two doses starting at
45 the second trimester with at least one month interval [3]. However, since October 2012, the policy
46 has been revised, and IPTp has been recommended at each scheduled antenatal clinical care visit
47 (ANC) from the second trimester of gestation, with the aim of ensuring the uptake of at least three
48 IPTp administrations of SP [5]. Several African countries have adopted the latest recommendation.
49 However, the uptake of the intervention is unacceptably low in areas of high-intensity transmission
50 of malaria [6], indicating the need of innovative tools and approaches to increase it.

51 With a rapid penetration of mobile phones in Africa, mobile health (mHealth) could be used as a
52 potential intervention to promote and enhance health care service utilization. Recent studies showed
53 that mHealth increase the utilization of maternal and child health services, clinic attendance, and
54 promote health-seeking behaviour [7]. Therefore, we aimed to evaluate the impact of mobile phone
55 intervention on the IPTp-SP uptake in Burkina Faso.

56 **Material and methods**

57 **Study design**

58 This was a pragmatic two-arms, open-label randomised trial carried out between November 2015 and
59 January 2017 at the health districts of Koudougou and Boulmiougou, Centre and Central-West health
60 regions of Burkina Faso. The 2 arms were composed of the intervention group (mobile phone use)
61 and the control group, which received only the routine ANC visit package.

62 **Study sites**

63 The study took place in the maternity clinics of Kokologo, in the health district of Koudougou
64 (Central-Western Region) and Tanghin Dassouri in the health district of Boulmiougou (Centre
65 Region). These sites were selected by convenience based on the geographical accessibility and their
66 rural (maternity clinic of Kokologo) and semi-rural (maternity clinic of Tanghuin-Dassouri)
67 characteristics. Most of the residents in the study areas are subsistence farmers with ‘mooré’ being
68 the most popular language. The climate is characterized by a long dry season running from October
69 to May, followed by a single short rainy season. Malaria transmission is perennial, with a peak period
70 of transmission running from June to September.

71 **Sample size**

72 Several studies carried out in Africa have reported that the proportion of women who received a third
73 dose of IPTp-SP was around 35% [8]. In Burkina Faso, data from the Ministry of Health showed that
74 68.6% of pregnant women received at least 2 doses of IPTp-SP in 2014 (one year before the start of
75 our study). We therefore assumed at 30% the proportion of pregnant women who will receive at least
76 3 doses of IPTp-SP in a routine situation, and this proportion would increase by at least 60% (an
77 increase from 30% to 48%) in a context of use of the mobile phone to relaunch appointments for
78 ANC visits. Under these assumptions, 230 pregnant women (115 per arm) were sufficient to observe
79 the difference of 18% (48% - 30%) due to the intervention with a power of 80% and a margin of error
80 of 5%.

81 **Study participants**

82 All pregnant women attending the ANC services were screened for participation in the study.
83 Pregnant women were enrolled if they had provided signed/thumb printed informed consent form,
84 had a gestational age at the first ANC < 20 weeks, had access to a mobile phone, had decided to reside
85 in study area throughout the period of the study and had agreed to comply with the study procedures.

86 **Intervention**

87 The mobile phone intervention consisted of making two systematic reminder phone calls for the ANC
88 visits appointment, the first and the second reminder calls one week and a day before the appointment
89 respectively. A standardised short text/voice message was delivered to those unable to be reached
90 out.

91 **Randomisation and masking**

92 Eligible and consenting pregnant women were randomly assigned (1:1) to either the mobile phone
93 intervention or control group. The allocation of the participants to the study arms was done centrally.
94 The principal investigator produced the computer-generated randomization list for each recruiting
95 site. Treatment allocation for each participant was concealed in opaque sealed envelopes that were
96 opened only after recruitment. Study participants were assigned a unique study number linked to the
97 allocated treatment group. Neither study participants nor clinical staff was masked because of the
98 nature of the intervention requiring overt participation.

99 **Outcomes**

100 The primary outcome was the proportion of pregnant women who received at least three doses of
101 IPTp-SP. Secondary outcomes were the proportion of pregnant women who attended at least four
102 ANC visits, the proportion of pregnant women with anaemia (Hb < 11 g/dL) at delivery, the
103 proportion of pregnant women with malaria infection (positive slide) at delivery, prevalence of low
104 birthweight (birthweight < 2500g) and the proportion of women who timely attended to their ANC
105 visits appointment. A woman was considered "regular" in prenatal consultation or "having a timely

106 attendance” when the date of consultation corresponded to the given appointment date.

107 **Procedures and data collection**

108 At the inclusion, demographic and socio-economic characteristics were collected and recorded in a
109 standardized case report form (CRF). Medical history including the obstetric history and chronic
110 conditions was also collected. Physical and obstetrical examination were performed. IPTp-SP was
111 administered to pregnant women with a gestational age > 13 weeks.

112 Blood sample by finger prick was collected at inclusion and at delivery for malaria parasitaemia and
113 haemoglobin concentration determination.

114 At delivery, the new-born was examined, and the Ballard’s score assessed to determine the gestational
115 age. A home visit was conducted within a week to women who delivered outside the health facility.

116 **Laboratory tests**

117 Haemoglobin (Hb) level was measured using a Hemo-Control photometer (EKF Diagnostics,
118 Barleben/Magdeburg, Germany) device with 10 µL of blood and anaemia was defined as Hb < 11 g
119 / dL. Malaria infection was determined using the Lambaréné technique [9]. Ten microliters of blood
120 were spread on a rectangular area of 1.8 cm² (1.8 cm x 1 cm) of a slide. The slide was stained with
121 Giemsa and read at a magnification of 1,000 with an oil immersion lens. A multiplication factor was
122 applied to the average parasitemia per field to determine the number of parasites per mL. The
123 Lambaréné technique detection threshold has been estimated to be 5 parasites per mL.

124 **Ethical statement**

125 The study protocol received approval from the Comité d’Ethique pour la Recherche en Santé
126 (Reference ID 2014-12-142) in Burkina Faso. The study was conducted in accordance with the
127 Declaration of Helsinki, Good Clinical Practice, and applicable national regulations. All study
128 participants provided written informed consent.

129 **Statistical analysis**

130 Data were managed with Microsoft Access 2013 and analysed with STATA software version 13.0
131 (Stata Corp, College Station, TX). Analyses were performed according to the intention-to-treat
132 population. We first describe the general characteristics of the study population. After then, univariate
133 and multivariate logistic regressions were performed to evaluate the impact of the intervention.
134 Because of the hierarchical structure of the data, we used generalised estimating equations to take
135 into account for within-sites correlation. Results were expressed as odds ratios (ORs) for primary and
136 secondary outcomes with 95% confidence intervals (95% CI). The statistical significance was set at
137 5%.

138 **Results**

139 A total of 1,569 pregnant women were screened. Of which, 248 were enrolled and data of 26 women
140 were analysed (Figure 1). At enrolment, the mean age of the study participants was 26.2 years, (SD
141 \pm 6.3) and 45.8% (99/216) pregnant women with a gestational age < 16 weeks attended the first ANC
142 visit. The study participants' general characteristics were similar between the study groups (Table 1).
143 The overall proportion of women who received at least three doses of IPTp-SP (the study primary
144 endpoint) was 54.6 % (118/216). The proportion of pregnant women who received at least three doses
145 of IPTp-SP in the intervention group (54.1%, 59/109) was not different from that observed in the
146 control group (55.1%, 59/107) (adjusted Odds Ratio; aOR: 0.86; 95% CI: [0.49 - 1.51]). There was
147 no significant difference between women who attended four ANC visits between the two groups:
148 93.6% (102/109) in the intervention group versus to 97.2% (104/107) in the control group (aOR:
149 0.40; 95% CI: [0.10-1.62]). Similarly, there was no difference between the two groups on the
150 secondary outcomes i.e. low birth weight, anaemia and malaria infection at delivery (Table 2).
151 However, women in the intervention group were more likely to timely attend the ANC visit
152 appointments than those in the control group (aOR: 3.21; 95% CI: [1.91-5.39]) (Table 3).

153 **Discussion**

154 Our results failed to depict an improvement in the coverage of the third dose of IPTp-SP, but they
155 showed a timely attendance of ANC visits appointments by pregnant women who were exposed to
156 mobile phones intervention at Kokologo and Tanghin Dassouri, in Burkina Faso.

157 Low coverage and poor quality of ANC visits are known to be associated with poor pregnancy
158 outcomes such as abortion, abnormalities, stillbirth, preterm birth, low birthweight and anaemia [10].
159 Evidence of interventions that improve the coverage and the quality of ANC visits is then crucial in
160 SSA, where the lowest rates of ANC visits attendance and IPTp-SP coverage are reported. [11]. The
161 ANC visits are essential to prevent and identify complications during pregnancy, improve maternal
162 and child outcomes [12,13] and especially, prevent malaria and malaria-related illness such as
163 maternal anaemia and placental malaria [12]. In this study, 54.6% of pregnant women had received
164 at least three doses of IPTp-SP. This result is substantially better than previous findings that reported
165 35% of pregnant women receiving three IPTp-SP doses in most African settings [8,14]. Although the
166 proportion of women who received at least 3 doses of IPTp-SP in our study is higher than those
167 reported by several African studies, it is still low compared to the available potential, since the
168 proportion of women who performed at least four ANC visits was 95.4%. IPTp-SP delivery is closely
169 related to the access of ANC visits. However, we observed an unexpectedly lower proportion of
170 women who received at least three doses of IPTp-SP despite the higher proportion of pregnant women
171 who completed at least four ANC visits. There are then important bottlenecks for high coverage of
172 IPTp-SP that should be considered such as the low socioeconomic status, high parity or unplanned or
173 mistimed pregnancies [15]. There are also social factors among young pregnant women such as
174 adolescents social position, acknowledgment of the pregnancy, health centre as public space who are
175 importantly related to the number of ANC visits [16]. Furthermore, although adopted by most national
176 malaria control programs in SSA, the effective implementation of the new policy of administering at

177 least 3 doses of IPTp-SP to pregnant women before delivery is not yet generalized in health facilities,
178 especially in peripheral areas.

179 Specific interventions that are included in the ANC visits package, if pushed to high coverage have
180 significant potential impact across many settings. In areas of high *P falciparum* burden, systematic
181 use of ITNs and/or IPTp-SP could reduce maternal mortality by up to 10%, newborn mortality by up
182 to 20%, and stillbirths by up to 25–30%; detection of pre-eclampsia followed by timely delivery could
183 prevent up to 25% of newborn deaths and stillbirth and over 90% of maternal eclampsia/pre-
184 eclampsia deaths [17]. In our study we failed to establish a significant relationship between the use
185 of mobile phone and the risk of adverse pregnancy outcomes such as low birthweight, anaemia and
186 malaria infection at delivery. However, a cluster-randomized controlled trial that investigated the
187 impact of mobile phones on antenatal care attendance in Zanzibar a semi-autonomous part of the
188 United Republic of Tanzania showed a trend towards more antepartum referrals amongst the
189 intervention group, suggesting that more women with complications were being identified and treated
190 [18].

191 Worldwide, fewer newborns are dying but they account for a higher share of child deaths and
192 estimates indicate that 14% of all deaths amongst children under five are due to preterm birth
193 complications [19]. As there is an association between few ANC visits and a subsequent preterm
194 birth, regular and timely attendance to antenatal care is essential to improve child survival [20]. In
195 line with the study conducted in Zanzibar [19], we showed that the use of the mobile phones was
196 associated with regular and timely attendance to ANC visits. The proportion of women who timely
197 attend their ANC visits was higher in the intervention group than in the control group. A cross-
198 sectional analysis performed on data of 4,494 mothers included in the Bangladesh Demographic and
199 Health Survey showed that women who use mobile phones are more likely to use ANC and
200 professional delivery services than those who do not [21]. The women may have used their own cell
201 phones during the survey; however, studies found an association between mobile phones ownership

202 and high socioeconomic level [22], which in turn affects women's ability to use health services [23].

203 The use of a mHealth intervention has been shown as a cost-effective strategy to promote prenatal
204 health [18,24–27]. However, in this study, there was no significant association between mobile phone
205 intervention and pregnancy adverse outcomes such as low birthweight, maternal anaemia and malaria
206 infection at delivery. Few studies in Sub Saharan Africa assessed the direct effect of the mHealth)
207 intervention on pregnancy outcomes [28,29]. Therefore, more in-depth assessments are needed to
208 explore the public health benefits of such an intervention.

209 There were some limitations in this study. First, we chose a pragmatic approach and randomised
210 individuals rather than health facilities leading to a potential spillover effect from intervention to the
211 control group. Second, most of the time, women do not have their own mobile phones and depend on
212 someone else, often their husband. Unfortunately, no information on cell phones ownership was
213 collected, so we cannot confirm that secondary outcomes were not confounded in the intervention
214 and control groups. Finally, we did not collect some potential confounder factors (parity, bed net use,
215 iron supplementation) which would have explained the lack of association, but we assumed that
216 factors have been distributed equally between the two study arms thanks to the randomisation.
217 However, we adjusted the analysis for unbalanced factors such as maternal education.

218 **Conclusions**

219 The mothers' mobile phones intervention significantly increased the proportion of women who
220 regularly and timely attend to their ANC visits, but the intervention did not increase the proportion
221 of women receiving at least 3 doses of IPTp-SP. The current evidence remains insufficient to
222 conclusively inform policy decisions and further quality research and cost-effectiveness analyses as
223 well as factors influencing the IPTp-SP intake are required to draw more robust conclusions,
224 particularly for poor-resource settings.

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227 workers, and the whole study team, including technicians, statisticians, students.,.

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232 influence the writing of the report and the decision to submit.

233 **Ethics approval and consent to participate**

234 The present study received approval from the Comité d’Ethique pour la Recherche en Santé
235 (Reference ID 2014-12-142). Women were included in the present trial after providing a signed
236 written informed consent.

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327 **Legends**

328 Figure 1. Study flowchart. ANC: Antenatal clinical

329 **Table 1:** general characteristics of study participants (N = 216)

Characteristics	Control group (n = 107)	Intervention group (n =109)	All (n=216)
Study site, % (n)			
Kokologo	65.4 (70)	64.2 (70)	64.8 (140)
Tanghin Dassouri	34.6 (37)	35.8 (39)	35.2 (76)
Age, Mean (SD) (year)	26.6 (±6.3)	25.8 (±6.3)	26.2 (±6.3)
< 20	13.1 (14)	22.0 (24)	17.6 (38)
20-30	61.7 (66)	56.0 (61)	58.8 (127)
≥ 30	25.2 (27)	22.0 (24)	23.6 (51)
Marital status, % (n)			
Single	0.9 (1)	2.7 (3)	1.8 (4)
Polygamy	23.4 (25)	27.5 (30)	25.5 (55)
Monogamy	75.7 (81)	69.7 (76)	72.7 (157)
Occupation, % (n)			
Housewife	46.7 (50)	50.5 (55)	48.6 (105)
Farmer	18.7 (20)	14.7 (16)	16.7 (36)
Business	21.5 (23)	22.9 (25)	22.2 (48)
Student	4.7 (5)	5.5 (6)	5.1 (11)
Civil servant	3.7 (4)	0.9 (1)	2.3 (5)
Others	4.7 (5)	5.5 (6)	5.1 (11)
Education, % (n)			
No	58.9 (63)	70.6 (77)	64.8 (140)
Yes	41.1 (44)	29.4 (41)	35.2 (76)
Household income, % (n)			
Low	43.9 (47)	51.4 (56)	47.7 (103)
Average	34.6 (37)	31.2 (34)	32.8 (71)
High	21.5 (23)	17.4 (19)	19.4 (42)
Gestational age (weeks)			
Mean	14.4 (±4.8)	14.6 (±4.6)	14.5 (±4.7)
<16	46.7 (50)	44.9 (49)	45.8 (99)
≥16	53.3 (57)	55.1 (60)	54.2 (117)
Hb level (g/dL) Mean (SD)	10.5 (±1.6)	10.3 (±1.6)	10.4 (±1.6)
<11 g/dL	57.6 (61)	61.7 (66)	59.6 (127)
Malaria infection, % (n)			
No	72.9 (78)	76.1 (83)	74.5 (161)
Yes	27.1 (29)	23.8 (26)	25.5 (55)
Number of IPTp doses, % (n)			
0	4.7 (5)	5.5 (6)	5.1 (11)
1	11.2 (12)	9.2 (10)	10.2 (22)
2	29.0 (31)	31.2 (34)	30.1 (65)
≥3	55.1 (59)	54.1 (59)	54.6 (118)
Number of ANC visit, % (n)			
1-3	2.8 (3)	6.4 (7)	4.6 (10)
≥4	97.2 (104)	93.6 (102)	95.4 (206)

330 Abbreviations: IPTp, Intermittent preventive treatment during pregnancy; Hb, Haemoglobin; ANC,

331 Antenatal care

332 **Table 2:** association between mobile phone intervention and primary and secondary outcomes, logistic multilevel mixed model (N=216)

Characteristics	Control	Intervention	Unadjusted OR (95% CI)	adjusted OR* (95% CI)
Primary outcome				
Number IPTp intake during pregnancy [£] ≥ 3 doses	59/107 (55.1%)	59/109 (54.1%)	0.96 (0.56-1.64)	0.86 (0.49-1.51)
Secondary outcomes				
At least four ANC visits	104/107 (97.2%)	102/109 (93.6%)	0.42 (0.11-1.67)	0.40 (0.10-1.62)
Anaemia at delivery	33/86 (38.4%)	31/78 (39.7%)	1.06 (0.56-1.98)	1.01 (0.53-1.91)
Malaria infection at delivery	0/81 (0%)	2/76 (2.6%)	-	-
Low birthweight	11/106 (10.4%)	10/104 (9.6%)	0.91 (0.37-2.26)	0.97 (0.39-2.42)

Abbreviations: OR, Odds ratio; IPTp, Intermittent preventive treatment in pregnancy; ANC, Antenatal care, anaemia defined as haemoglobin level <11g/dL. * Adjusted for maternal education and within cluster effect; £ At the first antenatal visit, no intermittent preventive treatment was administered

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343 **Table 3:** association between mobile phone intervention and regularity in the ANC visit appointment, logistic multilevel mixed regressions

344 (N=216)

Characteristics	Control	Intervention	Unadjusted OR (95% CI)	adjusted OR* (95% CI)
Regularity in the ANC visit appointment				
ANC visit 2	56/106 (52.8%)	84/109 (77.1%)	2.99 (1.67-5.39)	2.91 (1.61-5.26)
ANC visit 3	63/104 (60.6%)	70/101 (69.3%)	1.47 (0.82-2.62)	1.53 (0.84-2.77)
ANC visit 4	41/82 (50.0%)	63/87 (72.4%)	2.62 (1.38-4.97)	2.74 (1.43-5.27)
ANC visit 5	22/42 (52.4%)	37/42 (88.1%)	6.72 (2.21-20.5)	6.63 (2.17-20.2)
Overall ANC visits [‡]	182/334 (54.5%)	254/339 (74.9%)	2.49 (1.80-3.46)	3.21 (1.91-5.39)

Abbreviations: CI, Confidence interval; OR, Odds ratio; ANC, Antenatal care. * Adjusted for maternal education; ‡ Adjusted for within and inter individual effects

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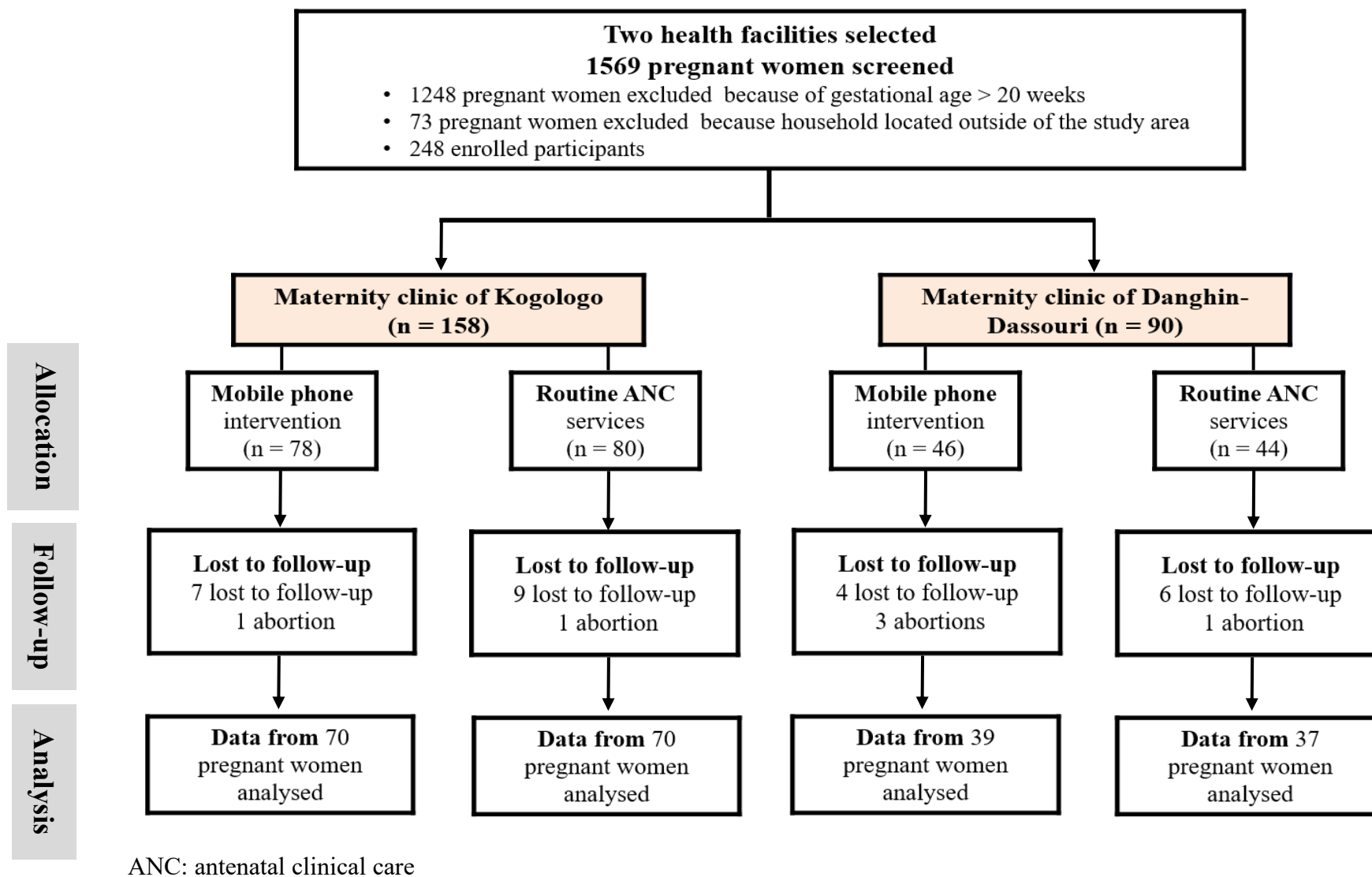


Figure 1: study flowchart