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Research Article

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Effectiveness of Public Health Education on the Uptake of Iron-And Folic Acid Supplements Among Pregnant Women: Findings from a Stepped Wedge Cluster Randomized Trial

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Abstract

Objective: *To determine the effectiveness of public health education on the uptake of iron and folic acid supplements (IFAS) among pregnant women.*

Design: *A stepped wedge cluster randomized trial.*

Setting: *12 antenatal care clinics (ANC) in Embu County - Kenya. The clinics are outpatient departments in health facilities dedicated to providing care for pregnant women.*

Participants: *Pregnant women receiving antenatal care services in the study sites.*

Intervention: *After a baseline observational phase, a multifaceted intervention bundle was implemented. The intervention included a 60-minute IFAS information session for health workers at the start of intervention. Health workers then provided daily IFAS literacy sessions to all the pregnant women and issued them with IFAS related information materials (a pill reminder card, and a personalized calendar). The study team conducted biweekly facility audits for quality assurance. The total duration of the study was 8 months, starting June 2022.*

Primary outcome: *The primary outcome was the proportion of pregnant women taking IFAS daily in the intervention phase compared with control phase. This was measured through IFAS residual pill count during every ANC visit.*

Results: *A total of 4,749 ANC visits were monitored for 2,132 women receiving antenatal care in the 12 clinics. Participant characteristics were similar across control and intervention phases. The uptake of IFAS significantly improved from 44.8% (95% CI 34.7 to 55.0) in control phase to 83.3% (95% CI 75.9 to 90.9) during the intervention. This translates to a 38.5 (95% CI 26.0 to 51.1) percentage points improvement. The number needed to treat (NNT) for this intervention was 3 patients (95% CI 2 to 4).*

Conclusion: *IFAS uptake significantly improved following the intervention. The findings support public health education as an effective strategy for improving the uptake of IFAS in ANC settings.*

Keywords: Iron Folic Acid, Public Health Education, Stepped Wedge Cluster Randomized Trial, Micronutrients, Pregnancy, Pill Reminder Card

1. Introduction

Iron deficiency during pregnancy increases the risk of anemia which is a leading cause of maternal deaths and adverse pregnancy outcomes. Antenatal iron deficiency has been associated with preterm births, low birth weight, perinatal mortality, poor neurological development, increased susceptibility to respiratory infections and childhood diarrhea, increased postnatal and under-five mortality, disrupted growth in adolescent mothers, and permanent disability for millions of children [1-4]. Over half (62%) of pregnant women in Kenya are anemic, with rural areas being disproportionately affected (50.8% of pregnant women in rural areas are anemic compared to 29.5% [5-7]. Furthermore,

10% of maternal deaths and 20% of prenatal deaths in Kenya are attributable to anemia [8].

In populations at risk of iron deficiency, the World Health Organization recommends daily intake of 60 mg iron and 400 µg of folic acid as a standard of care for anemia prevention in pregnancy. However, overall global progress in reducing the burden of anemia has been slow and uneven with less than half of pregnant women taking IFAS satisfactorily [5]. For instance, the proportion of pregnant women receiving iron supplements in Kenya improved only by a paltry 0.7 percentage points from 68.7% in 2008 to 69.4% in 2015. In 2015, just 7.5% took IFAS for 90 days or more, a mere five-percentage points improvement from 2.5% reported in 2008 [9,11].

Educating patients increases their knowledge and improves preventive behaviors. Better knowledge on the dangers of anemia, and the protective effect of IFAS boosts IFAS uptake [12,13]. Other studies have shown improved uptake of preconception IFAS and better dispensing of IFAS following public health education [8,14-18]. While women are aware of the symptoms of anemia in pregnancy, many do not feel at risk of anemia and are thus not motivated to take IFAS [19,20]. Among the noted deterrents of IFAS uptake is the absence of job aids, staff attitude, adequacy of IFAS counselling and limited frequency of contact with the healthcare system [13]. Sensitizing health workers and issuing job aids is therefore key for effective patient education [13,21,22]. It makes them aware of the guidelines and facilitates their discussion with patients, thus stimulating patients' behavior change [23,24]. It is recommended that related health interventions should be deployed as a bundle for synergy and consistent delivery of best practices as a set [25,26]. However, there is limited literature on the effectiveness of public health education on the uptake of IFAS by pregnant women in ANC setting [24,27,28].

Embu County was suitable for the study due to the low uptake of IFAS among pregnant women. Only 6% of pregnant women consumed IFAS for at least 90 days and one in every six pregnant women had anemia [10]. The absence of ongoing IFAS-related health education activities in the county plus the predominantly rural setting reduces the chances of contamination of the intervention from the social- and mainstream media [29]. Health education was implemented as a bundle of multifaceted interventions targeting health workers and pregnant women as outlined in the maternal IFAS awareness (MIA) study protocol [30]. The aim of the MIA trial was to determine the effectiveness of public health education on the uptake of IFAS among pregnant women receiving antenatal care services in health facilities in Kenya.

These findings provide an overall picture of IFAS uptake in the study area and serve as practical resource for improving the uptake of IFAS and other health facility based health services in resource-limited settings. Improving IFAS uptake would accelerate global progress towards ending hunger and all forms of malnutrition, and the 2025 global nutrition targets.

The study was approved by the Kenyatta University Ethical Review Committee and registered in the Pan African Clinical Trial Registry [31,32].

2. Methods

2.1. Study Design and Participants

A stepped wedge cluster randomized trial (swCRT) was used with ANC clinics as units of randomization. This design is recommended for evaluating outcome of interventions implemented as part of routine healthcare, particularly where individual randomization is impractical for ethical reasons [33]. The duration of the study was eight months. Clusters were randomly allocated to one of the seven steps. with two facilities crossing over at a time except for the first and last months when only one facility crossed from control to intervention phase (Figure 1).

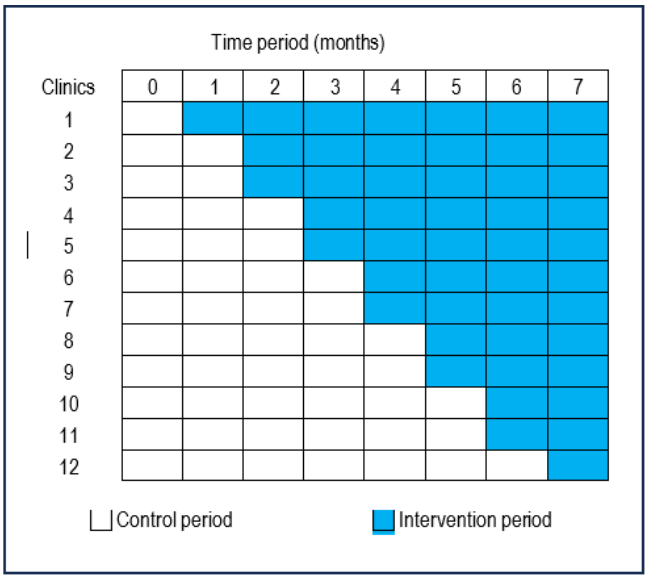

Figure 1: Diagrammatic Illustration of the Stepped Wedge Design

Unshaded cells represent data gathering in health facilities during the control period. Shaded cells represent data gathering in health facilities during the intervention period.

The levels of IFAS uptake were assessed at baseline and monitored during monthly ANC visits by counting the left over IFAS pills. Those taking IFAS every day for all visits were given an overall score of 1, and 0 for those who had pill balances in any ANC visit.The study was implemented in Embu County, Kenya. The county has high prevalence of anemia in pregnancy and low uptake of antenatal IFAS. Twelve public facilities providing ANC services participated in the study [10,29].

Participating health facilities collected data for all pregnant women receiving antenatal care. Owing to the nature of the intervention, all participants seeking ANC services received the same care package during the intervention phase.The eligibility criteria for health facilities included: (i) ability to enroll at least 21 new pregnant women per month, (ii) having complete health records, (iii) eligibility to receive IFAS supplies from the Ministry of Health, and (iv) willingness of facility management

and staff to participate in the study.

2.2. Recruitment

No clusters were lost or excluded, and all received the intervention as per protocol. All pregnant women seeking antenatal care services at the selected facilities between 01 June 2022 and 31 January 2023 were recruited and provided with the intervention package. The trial ended once all the clusters had been recruited and followed as stipulated in the study protocol [30].

2.3. Randomization and Binding

All facilities started the trial at the same time point (June 2022) and acted as controls until such time as they were randomized to crossover from control to intervention. The point at which each of the 12 facilities transitioned from control to intervention was determined through simple randomization using computer generated random numbers (generated by principal investigator). Facilities were informed of the start date one month before the intervention to minimize contamination. The study team activated the engagement activities (baseline assessment and message customization) during this month. Due to the nature of the intervention, it was not possible to blind participants or health workers to the intervention. However, names of participating facilities and randomization sequence was concealed to all except the investigators.

2.4. Intervention

The MIA study intervention entailed three components: (i) one-off 60-minute IFAS information sessions (supplemental Table 1) with ANC service providers at the start of the trial delivered during the lunch hour to minimize interruption of service delivery, (ii) ANC service providers giving IFAS literacy sessions to pregnant women at ANC clinics every day (thus women received one session per month since ANC clinic visits have a monthly frequency), and (iii) Providing information, education and communication (IEC) materials notably the pill reminder card (PRC) and MIA wall charts with personalized ANC clinic return dates) to pregnant women. The IEC materials for the trial (Box 1) were adapted from the national IFAS program and customized to fit the local context based on evidence from the facility baseline assessment.

The full spectrum of the interventions (Box 2) was enhanced through study-specific roles of service providers (Box 3). Biweekly health facility spot-checks, and monthly audits were used to monitor execution of the study including availability of study supplies and continuity of counselling. Adherence to the intervention was enhanced through counselling, pill reminder cards (PRC) and the MIA calendars. The duration of the awareness session varied depending on the issues raised by a participant, and health worker's judgement of her understanding of the concept.

Box 1: Study IEC materials

The pill reminder card (PRC): The card was stapled on the IFAS envelope and served as an aide-memoir for participants to take IFAS every day. It contained all the days between ANC visits, so the participant could mark after taking the pill daily. A health worker reviewed the card at every visit and counselled the participant accordingly. The reverse side of the card had messages on anemia and antenatal IFAS.

MIA study IFAS envelopes: Envelopes containing IFA pills were issued to study participants at every scheduled ANC visit. For assessing adherence, participants were given two extra pills. It was expected that adhering participants would return exactly two pills. The number of pills in each envelope was blinded to the participants. The only instruction on the envelope was to take one pill per day.

MIA wall calendars: The calendar was issued to the participants during their first contact with the ANC clinic and served as a participant's reminder of the importance of antenatal IFAS, and ANC visit dates. The health worker clearly marked all the ANC return dates on the calendar so the participant can remember the clinic appointments, where among other services IFA supply would be replenished, a count of remaining pills done, and PRC reviewed. Messages in the wall calendar were adapted from the national IFAS IEC materials.

Facility wall charts: The national IFAS program wall chart on the benefits of IFAS and the recommended doses was printed and distributed to health facilities. This is because printed wall charts on IFAS are not always available in health facilities.

Box 2: Components of the MIA intervention

Control period: Current standard of care. Women were given general health education at the triaging room; ANC clinic return dates are recorded in the mother-child booklet and HF appointments' diary, and IFAS issued at dispensing unit without any emphasis on IFAS or ANC return dates.

Intervention period: The following six study-specific interventions were implemented for health workers and the pregnant women, in addition to three cross-cutting interventions.

Health workers

1. Overview of IFAS rationale, dosing schedule, pill reminder card.
2. MIA slides with key points to use during health talks.
3. MoH algorithm for counselling on antenatal IFAS.

Pregnant women

1. Morning health talks on the risk of anemia in pregnancy, IFAS benefits and dosing, mitigation of IFAS side effects.
2. Emphasis on ANC return dates for IFAS refill reinforced through wall calendars with well-marked ANC return dates.
3. Pill reminder cards and guidance on their utility to facilitate continuous IFA uptake.

Crosscutting (facility level) interventions

1. Sufficient supply of IFA supplements.
2. Biweekly health facility spot-checks.
3. Monthly audits and feedback by study and County health team.

Box 3: Summarized role of the health workers during the study

Triaging and history taking room: Initial contact group talk: Discuss the prevalence, dangers and signs of anemia in pregnancy, how anemia can be prevented and treated using IFAS. The IFAS schedule, potential side effects and how to mitigate them. Importance of ANC. Issue ANC booklet to new mothers and emphasize importance of adhering to ANC visits highlighting the importance of the service that she would receive at every ANC visit.

Examination room: Ask if she knows about anemia, its signs and prevention, assess and augment her knowledge on IFAS. Advise her on IFAS (schedule, importance, safety, management of potential side effects), emphasize importance of IFAS for her and unborn child.

For revisiting participants: Count the remaining pills and record in the ANC register, advise her to finish the balance before starting the new supply. Examine and take a photo of the pill reminder card (PRC) and cross out past periods to avoid mistaken entries. Remind her how to use the PRC.

For first visit participants: Issue MIA wall calendar, mark all clinic return dates and explain the importance of honoring the ANC visits.

Resolve any challenges that she has on IFAS and anemia. Update ANC register with details of the services provided to her.

IFAS dispensing room: Issue IFAS, advise on when and how to take IFAS, potential side effects and how to manage them, request her to bring any remaining pills in the next visit, or continue taking the remaining pills should she deliver before the next ANC visit. Issue PRC to first visit participants, orient her how to use PRC as an aide-memoire, and request her to bring it during the next clinic visit. Remind her the date of the next ANC clinic.

2.5. Outcome

The primary outcome was the proportion of pregnant women effectively taking up IFAS. This was determined by counting the residual IFAS pills during ANC follow up visits. Cluster level uptake was determined by calculating the proportion of women who had taken all pills in a particular cluster. The levels of IFAS uptake observed before the intervention served as the control values for the trial.

2.6. Statistical Analysis

To detect a 50% increase in IFAS uptake at a power of 80% and a coefficient of variation of 0.25, the minimum number of clusters required to make reasonable references about the effect of the intervention was estimated based on the method proposed by Hayes [34]. Twelve clusters were recruited to protect against pre-randomization exclusions and non-response [30]. For participant characteristics, frequencies and percentages were used to present discrete data. Continuous variables were presented using mean and standard deviations.

Cluster level analysis was used as recommended for trials with small number of clusters. The t-test statistic was used to compare the changes in uptake between intervention and control phases based on means of unweighted cluster-level summaries, assuming unequal variances with two independent samples t-test [35]. The t-test was also carried out for the different sociodemographic groupings. The number needed to treat, and preventable fraction was used to quantify the effect of health education on IFAS uptake. All statistical analysis were performed using Stata version 17. The precision of estimates was determined using p-values and 95% confidence intervals (CI). $p < 0.05$ was considered statistically significant.

2.7. Trial Registration and Ethics Approval

The trial was registered in Pan African Clinical Trial Registry (PACTR202202775997127), permit from National Commission for Science, Technology and Innovation (NACOSTI/P/22/16168), and clearance from the County health authorities.

Ethical approval was granted by Kenyatta University Ethics Review Committee (PKU/2443/11575). Written informed

consent was obtained from pregnant women and the health facility in-charges. The facility in charges provided written informed consent on behalf of the cluster. A sub-sample of participants selected for the knowledge assessment exit surveys provided written informed consent.

2.8. Deviations from the Protocol

The trial covered all sub counties in Embu since no sub county could solely yield the required number of clusters as per study inclusion criteria. The key informant interviews with health managers were not done as this would have led to contamination of the intervention. The last cluster was followed up for one month instead of the planned two months, since uptake was already at 100 percent, which was expected to be sustained based on the observed trends from the other clusters (Figure 2). There were no changes to trial interventions or outcome measures.

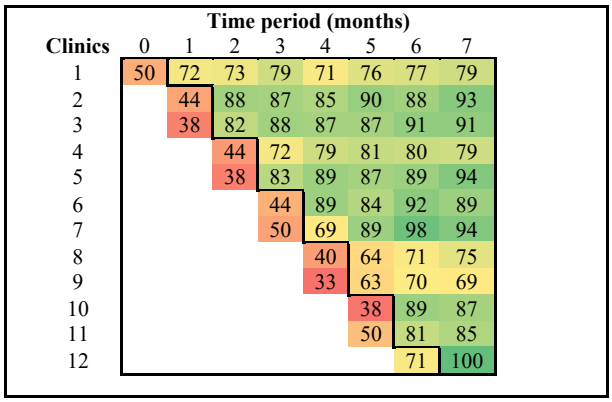

Figure 2: IFAS Uptake Rates by Step and Health Facility
The percentages to the left of dark border represent IFAS uptake levels during the control period. Percentages to the right of the dark border reflect IFAS uptake during the intervention period.

2.9. Patient and Public Involvement

Participants and the public were not involved in the development of study protocol. However, they were involved in design and implementation of the intervention: Feedback from baseline survey was used to customize health information, and the health workers were the sole implementors of the study interventions. The study findings were disseminated to the health managers during the MIA dissemination workshop.

3. Results

3.1. Characteristics of Respondents

The 12 study sites registered a total of 11,569 ANC visits between June 2022 and January 2023. Over half of these visits (6,881;59.5%) occurred during the intervention phase, out of which 2,132 were first time post-intervention visits, hence did not yield data for IFAS uptake assessment. Thus data from 4,749 visits was available for analysis of the study outcome. A total of 2,132 unique participants were enrolled in the MIA trial. The mean age of study participants was 25 years, most were married (78%), unemployed (64%), lived in rural areas (66%), nulliparous (60%), and had started ANC at 16 weeks. Characteristics of the participants were similar across the control and intervention phases (Table 1).

Characteristic	Frequency	Percentage
Age (years)		
20 years and above	1,812	85.0%
Below 20 years	320	15.0%
Marital status		
Married	1,662	78.0%
Not married	470	22.0%
Level of education		
Primary	853	40.0%
Secondary	938	44.0%
College	341	16.0%
Place of residence		
Rural	1,408	66.0%
Urban	724	34.0%
Employment status		
Employed/business	766	36.0%
Unemployed	1,366	64.0%
Parity		
Multiparous	852	40.0%
Nulliparous	1,280	60.0%
Gestation age at first ANC		
Within the first 12 weeks	510	38.0%
After 12 weeks	1,622	62.0%

Table 1: Sociodemographic Characteristics of Participants

3.2. IFAS Uptake among Pregnant Women

All pregnant women in the trial were issued with IFAS tablets containing 60 mg iron and 400 µg folic acid. The IFAS uptake was estimated at 44.8% (SD 49.98) at baseline and 83.3% (SD 37.46) following the MIA intervention, a difference of 38.5 (95% CI 26.0 to 51.1) percentage points. The effect of the intervention was immediate and was sustained throughout the intervention period across all the clusters (Figure 2).

The effect of the MIA intervention was significant across the various sociodemographic characteristics, except among the teenage and the unmarried women where the evidence was weak (Table 2). The effect was greatest among those with secondary level of education at 44.8 (95% CI 26.7 to 62.9). However, only the observed difference of 32.9 between the teenage and non-teenage women (data not shown) was statistically significant (95% CI 2.3 to 78.5; p value 0.02).

Characteristic	Intervention [α]	Control [α]	Difference (95% CI)	*p* value
Age				
20 years and above	83.5 (37.3)	40.2 (49.3)	43.3 (30.0 - 56.6)	< 0.001
Below 20 years	81.8 (42.5)	71.4 (46.9)	10.4 (-26.5 - 47.2)	0.28
Marital status				
Married	85.0 (35.9)	44.0 (50.0)	41.0 (27.3 - 54.7)	< 0.001
Not married	75.0 (44.7)	47.6 (51.2)	27.4 (-5.3 - 60.1)	0.0489
Level of education				
Primary	81.6 (39.3)	52.6 (53.6)	28.9 (8.2 - 49.7)	0.0034
Secondary	86.7 (34.4)	41.9 (49.9)	44.8 (26.7 - 62.9)	< 0.001
College	76.9 (43.9)	33.3 (48.8)	43.6 (7.3 - 79.9)	0.0102
Place of residence				
Rural	82.1 (38.6)	46.0 (53.2)	36.1 (20.6 - 51.6)	< 0.001
Urban	86.2 (35.1)	42.4 (52.2)	43.8 (21.5 - 66.1)	< 0.001
Employment status				
Employed/business	73.5 (44.8)	42.8 (56.2)	30.7 (7.8 - 53.6)	0.0047
Unemployed	88.7 (31.9)	45.9 (50.2)	42.8 (27.8 - 57.8)	< 0.001
Parity				
Multiparous	77.8 (42.2)	44.7 (54.4)	33.0 (11.4 - 54.6)	0.0016
Nulliparous	86.7 (34.3)	44.8 (53.2)	41.8 (26.2 - 57.5)	< 0.001
Gestation at first ANC				
Within first 12 weeks	74.2 (44.5)	41.6 (57.0)	32.5 (9.3 - 55.8)	0.0034
After 12 weeks	87.7 (33.1)	46.6 (57.3)	41.0 (26.1 - 56.0)	< 0.001
Overall	83.3 (37.5)	44.8 (50.0)	38.5 (26.0 - 51.1)	< 0.001

α: Mean and standard deviation

Table 2: Uptake of Antenatal IFAS by Sociodemographic Characteristics

3.3 Effectiveness of Public Health Education on IFAS Uptake

The public health importance of the intervention was quantified through attributable fraction. It was estimated that 46% (95% CI 32 to 58) of the improvement in IFAS uptake was due to the intervention. The number needed to treat (NNT) was used to assess the effectiveness of public health education. The study had an estimated NNT of three (95% CI 1.96 to 3.84) pregnant women.

4. Discussion

The results of this study show that public health education in an antenatal care setting is effective in improving the uptake of IFAS among pregnant women. Following the MIA intervention, the levels of IFAS uptake improved from 44.8% to 83.3%. An estimated 46.3% of the observed improvement in IFAS uptake was attributable to the MIA intervention. In terms of effectiveness, the trial had an NNT value of 3. Considering the challenge of adopting a new behavior, and the significant benefits for the pregnant woman, this NNT seems sufficient.

The provision of PRCs reinforced the daily IFAS consumption, while the personalized wall calendars continuously reminded them of the next date for ANC clinic, during which they would refill their IFAS supplies, learn more about IFAS, and share experiences and motivation with other women. Health workers were also provided with IEC materials and a structured way of communicating about IFAS to pregnant women, with a focus on the importance of IFAS, potential side effects, and mitigation of the latter. These findings are consistent with previous studies that have explored the relationship between knowledge and IFAS uptake as well as the importance of visual aids for health workers and patients [8,36]. This study uniquely focused on pregnant women receiving ANC services in a resource-constrained setting thus expanding the evidence base in such settings [13,21,22].

The implications of these findings are promising. Implementing

a multifaceted public health education program in ANC clinics can equitably improve the uptake of IFAS in pregnant women irrespective of the women's socio-demographic characteristics. Evidence from implementation science suggests that related interventions should be deployed as a bundle for consistence and synergy, and that behavior change techniques should be deployed in multiples, a salient feature in the MIA trial.The MIA trial has several strengths – most notably is the scale in observing 11,569 ANC care visits over a period of 48 implementation months, coupled with robust randomization process and the use of the swCRT design which minimizes the effect of confounders [24,27,28,37,38]. Providing the intervention as part of routine healthcare in a resource-constrained setting allows generalization of the findings in other low-income countries and similar settings.Notable limitations of the MIA trial include the use of pill count as a proxy indicator for IFAS uptake which is subject to manipulation by participants, as participants could throw away pills on some days.

The results of this swCRT are promising, suggesting that health education can significantly increase the uptake of antenatal IFAS. Importantly, combining health education with supportive tools like PRCs and personalized wall calendars proved effective in reminding women to take IFAS daily and ensuring timely resupply. The PRCs further empowered women to actively monitor their IFAS intake, potentially fostering sustained engagement throughout pregnancy. This comprehensive approach fostered active participation from both women and healthcare workers, promoting greater IFAS uptake. Future research should incorporate biochemical indicators like blood hemoglobin levels, and assess the long-term effects of IFAS uptake such as prematurity, low birth weight and neonatal outcomes. Expanding research to recruit more clusters across diverse geographical regions would enable more robust analysis.

Data Availability Statement

The MIA trial dataset can be made available upon request to the corresponding author.

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Author Contributions

HN conceived and designed the study. HN, EN, MW were involved in the development and implementation of the study, HN and EN supervised the data collection team, HN performed the data analysis and drafted the manuscript. HN, EN and NW contributed to the interpretation of results. All authors critically revised and approved the final manuscript. HN is responsible for the overall content as guarantor.

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Competing Interests

The authors have no financial or other competing interests to declare.

Trial registration

PACTR202202775997127.

Strengths and Limitations of this Study

• The study design offered the advantage of providing a public health intervention to all study participants with minimal risk of contamination.

• The intervention was provided only to pregnant women seeking services in public health facilities who may be socioeconomically different from those not seeking antenatal care.

• Uptake was evaluated based on residual pill count, which does not account for the possibility that participants may discard IFAS pills.

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