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Effectiveness of public health education on the uptake of iron and folic acid supplements among pregnant women: a stepped wedge cluster randomised trial

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ABSTRACT

Introduction Iron deficiency is the most prevalent micronutrient deficiency in pregnancy globally responsible for nearly 120 000 maternal deaths per year and a fifth of maternal mortality. Over 46% of pregnant women in Africa and 62% of pregnant women in Kenya are anaemic. Anaemia has severe economic and health consequences. Daily iron and folic acid supplementation (IFAS) is an efficacious strategy recommended in pregnancy to reduce the risk of anaemia and improve maternal and neonatal survival. However, most pregnant women do not consume IFAS as recommended. Limited knowledge on IFAS, its benefits and its connection with anaemia, and mitigation of its side effects lead to poor consumption. The main objective of this trial is to determine the effectiveness of public health education on uptake of antenatal IFAS.

Methods and analysis A stepped wedge cluster randomised trial with antenatal clinics as units of randomisation. Twelve clusters will be randomised to receive the intervention and levels of IFAS uptake compared with preintervention period. The 9-month trial will enrol 1205 pregnant women. The primary outcome will be the proportion of pregnant women effectively taking up IFAS measured through self-reports, residual pill count and inspection of pill reminder cards. Routine clinical data on haemoglobin counts and fetal growth monitoring will also be used. Descriptive and bivariate analysis will be conducted in Stata using Pearson's χ^2 test for association, and multivariate logistic regression to identify determinants of uptake. The potential public health benefits will be estimated using the number needed to treat and the preventable fraction.

Ethics and dissemination Ethical approval was granted by Kenyatta University Ethics Review Committee (PKU/2443/11575). The research permit is obtained from Kenya National Commission for Science, Technology and Innovation (NACOSTI/P/22/16168). Findings will be disseminated through peer-reviewed publications and public health conferences.

Trial registration number PACTR202202775997127.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study sample will only be pregnant women in health facility settings which may limit the generalisability of results.
⇒ Outcome data will be collected from primary and secondary sources for complementarity.
⇒ Some data is based on self-reports which is prone to social desirability bias.
⇒ The study will employ a bundled set of intervention targeting both the health workers and pregnant women for synergy.

INTRODUCTION

Background

Globally it is estimated that about 2 billion people are micronutrient deficient with children, pregnant and lactating women often experiencing multiple deficiencies.[1] Requirements for most micronutrients increase during pregnancy and lactation due to the rapid multiplication of placental and fetal tissues in pregnancy, and metabolic demands for milk production during lactation.[2] The daily recommended dietary allowance for iron and folate increases by 50% during pregnancy from 18 mg to 27 mg and from 400 µg to 600 µg for iron and folate, respectively.[3] This demand cannot be resolved solely through diet.

Iron deficiency is the most prevalent and the most serious micronutrient deficiency in pregnancy. Globally, 38.2% (or 32.4 million) pregnant women are anaemic.[4] This makes anaemia the most common medical disorder in pregnancy. Prevalence is estimated at 42.7% in low/middle-income countries (LMICs)[5] and 22% in high-income regions.[4] Over a third (36%) of pregnant women in East Africa[4] and over half (62%) of pregnant women in Kenya are anaemic.[6]

Deficiency of iron and folic acid (IFA) during pregnancy increases the risk of anaemia which is a leading cause of maternal deaths and adverse prenatal, maternal and lifelong outcomes with a negative impact on society and economy. Iron deficiency is the most common cause of anaemia worldwide responsible for 50% of anaemia in pregnant

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women.[4] Iron deficiency anaemia contributes substantially to death and disability in women. Globally, anaemia is directly responsible for nearly 120 000 maternal deaths[7] and 3.4 million DALYs in women.[8] Pregnant women with severe anaemia are twice as likely to die during pregnancy and post partum.[9] In Kenya, 10% and 20% of maternal and prenatal deaths respectively are attributable to anaemia.[10] It is estimate that 12% of low birthweight babies, 18% of perinatal mortality, and nearly 0ne in every five preterm births in LMICs are attributable to maternal anaemia.[5] Furthermore, the risk of postnatal and under-5 mortality is elevated for children whose mothers missed antenatal iron and folic acid supplementation (IFAS).[11] Additionally, antenatal IFA deficiency has been associated with irreversible damage to the brain, poor neurological development, increased susceptibility to childhood diarrhoea and respiratory infections due to impaired immune system,[12 13] and disrupted growth in adolescent mothers.[14] In many parts of the world, millions of children are permanently disabled by the physical and mental effects of poor intrauterine iron intake.[15]

IFAS is an effective high impact intervention for enhancing iron stores and preventing anaemia in pregnancy (AiP). The WHO recommends 60 mg of iron and 400 µg/day of folic acid daily as a standard of care for anaemia prevention in pregnancy.[15] In many countries, this is provided as a fixed-dose tablet through antenatal care (ANC) clinics. A daily iron dose of 120 mg is recommended for the treatment of anaemia until 110 g/L is achieved. In Kenya, 96% of pregnant women visit ANC clinics,[16] and IFAS is available free of charge to pregnant women through ANC clinics in public health facilities (HFs).

Nearly one out of every five (19%) maternal deaths can be prevented through antenatal iron supplements,[17] including halving the risk of neonatal death (HR=0.49), 70% and 19% reduction in anaemia and incidence of low birthweight babies, respectively.[18–20] Likewise, antenatal folic acid reduces the risk of underweight births, pre-eclampsia, placental abruption, preterm births, small for gestational age infants and birth defects, with better academic scores.[21 22]

The overall global progress in decreasing anaemia has been slow and uneven with less than half of pregnant women taking IFAS satisfactorily.[23] Kenya planned to raise ANC IFAS coverage and usage (90+ pills) to 80% and 30%, respectively by end of 2017.[10] However, only 48% coverage was achieved.[24] The proportion of pregnant women receiving iron supplements in Kenya improved only by a paltry 0.7% from 68.7% reported in 2008 to 69.4% in 2015. Similarly, just 7.5% took supplements for 90 days or more. This was a mere 5 percentage points improvement from 2.5% reported in 2008.[16 25]

There is a positive correlation between levels of knowledge and perceived severity and personal susceptibility to micronutrient deficiency.[26] Knowledge on the dangers of anaemia, and the protective effect of IFAS boost IFAS uptake.[10 27–31] Paradoxically, while women are aware of the symptoms of AiP, many do not feel at risk of anaemia and thus no motivation to take supplements.[26] Dietary taboos and cultural misconceptions requiring pregnant women to purposefully eat less aiming to have smaller babies, and the fear that IFAS would increase fetus size leading to costly birth complications, hinders IFAS uptake.[32 33] In addition, maternal characteristics such as inconsistent ANC attendance, forgetfulness, maternal age, gravidae, low socioeconomic status, taste and side effects of iron-containing tablets are documented barriers to IFAS uptake.[4 31 34] Health systems characteristics such as waiting time, presence of job aids, efficiency of the IFAS supply system, staff attitude, adequacy of IFAS counselling and frequency of contact with the healthcare system also affects uptake of antenatal IFAS.[26 35 36] In the absence of IFAS, many pregnant women turn to geophagy, which has significant risks to them and the fetus.[37]

Health education is integral in social marketing.[38] A meta-analysis of trials evaluating patient education showed that self-monitoring (through pill reminder cards (PRC)), supportive materials and multiple communication channels improve preventive behaviours.[39] Furthermore, continuous health education increases knowledge and improves favourable behavioural change.[26] Health workers should also be sensitised for successful implementation. The behaviour of healthcare providers is influenced, inter alia, by awareness of guidelines, product availability and presence of memory aids.[40] Providing information, education and communication (IEC) materials facilitates staff discussion with patients and improves their skills and confidence to deliver interventions.[41 42] As posited in social cognitive theory of behaviour change, this confidence stimulates behaviour change among patients.[43 44] Evidence from implementation science shows that related health interventions should be deployed as a bundle for reliable delivery and synergy.[42 45 46] Furthermore, greater success is achieved by deploying multiple behaviour change techniques.[47 48]

Anaemia in women of reproductive age remains a public health problem globally. The global nutrition target for 2025 is to achieve a 50% reduction of anaemia among women of reproductive age, 30% reduction in underweight births and 40% reduction in the number of children under-5 years who are stunted compared with the 2011 baseline.[4 49] Better antenatal IFAS uptake would improve maternal and child survival, sustain the gains made by the country on the first, fourth and fifth Millennium Development Goals, contribute towards the second Sustainable Development Goal's target of ending hunger and all forms of malnutrition by 2030,[50] and contribute towards the first three (of the six) 2025 global nutrition targets.[49]

Objectives

The main objective of the maternal IFAS awareness (MIA) trial is to determine the effectiveness of public health education on uptake of IFAS among pregnant women. The specific objectives are to: (1) establish IFAS uptake

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among women attending ANC clinics, (2) determine the sociodemographic predictors of IFAS uptake among pregnant women attending ANC clinics, (3) determine the effect of public health education on IFAS knowledge, attitudes and uptake among pregnant women and (4) determine the association between IFAS knowledge and uptake among pregnant women.

Trial design

The MIA study is designed as a stepped wedge cluster randomised trial. This design is apt for evaluating outcome of interventions implemented as part of routine healthcare, particularly where individual randomisation is impractical for ethical, logistical or fiscal reasons.[51] Participants will be randomised in clusters (ANC clinics). All clinics will begin as controls and crossover to intervention at different time points in random order until all clinics receive the intervention. Before the trial, a baseline cross-sectional survey will be conducted among pregnant women attending ANC clinics, health managers at county, subcounty and facility level, and among health workers attending ANC clients to inform the customisation of public health education messages.

METHODS

Study setting

The study will be conducted in Embu County in Kenya. The county has been purposely selected owing to the low uptake of IFAS, high prevalence of AiP and low ANC clinic completion rates.[16 24] Subcounties with the lowest uptake of antenatal IFAS 12 months preceding the trial will be eligible. All pregnant women receiving ANC in the selected HFs will receive the intervention.

Eligibility criteria

The eligibility criteria for HFs will be: (1) ability to enrol at least 21 new pregnant women per month, (2) having complete health records (ANC register and bin cards), (3) eligibility to receive IFAS supplies from the Ministry of Health (MoH) and (4) willingness of HF management and staff to participate in the study.

The following will be excluded from the trial (1) HFs whose management will not consent to participate and (2) pregnant women receiving care from non-consenting HFs.

Intervention

The MIA study intervention is grounded on the social cognitive theory of behaviour change.[44] The intervention will entail (1) IFAS information sessions with all ANC service providers delivered in 60 min lunchtime sessions as outlined in table 1 to minimise interruption of service delivery, (2) daily IFAS literacy sessions with pregnant women and (3) providing IEC materials (PRC and MIA wall charts) to pregnant women. The wall charts will be prepopulated with IFAS messages and personalised ANC clinic return dates.

The IEC materials for MIA study (box 1) will be adapted from the national IFAS programme documents and customised to fit the local context based on evidence from the baseline assessment. For synergy, the study intervention will be provided as a bundle[45] containing 10 interdependent components (table 2) enhanced through study-specific roles of service providers (table 3). Site spot-checks will be used to monitor execution of the study including availability of supplies and continuity of counselling sessions. Adherence will be enhanced through counselling, PRC and individual ANC calendars.

Outcomes

The primary outcome is the proportion of pregnant women effectively taking up IFAS. This will have two dimensions—initial uptake and continuous uptake. Initial uptake will be measured by possession of IFAS confirmed by visual inspection and corroborated with data from DHIS, ANC register (MoH 405) and IFAS bin

Table 1 Focus areas for health workers' sensitisation

Topic	Objectives	Requirements	Duration (minutes)
Antenatal care	Importance and expectations per visit	MoH ANC guidelines	15
Anaemia in pregnancy	Magnitude of the problem in the study area. Prevention and treatment	MoH IFAS guidelines. Slide handouts from baseline survey	15
IFAS	National guidelines Baseline findings Common side effects Mitigation of side effects	Slides from baseline survey Slides on national guidelines Slides on IFAS side effects	15
The MIA study	Objectives of the MIA study Orientation on MIA IEC materials Role of service providers (table 3)	Copies of IEC materials (box 1)	20
Q&A	Address any questions	None	5

ANC, antenatal care; IEC, information, education and communication; IFAS, iron and folic acid supplementation; MIA, maternal IFAS awareness; MoH, Ministry of Health.

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Box 1 Study IEC materials

Pill reminder card
This will serve as an aide-memoir for pregnant women to take IFAS every day. The card which will be bearing client's ANC card number for linkage with other datasets will be stapled on the IFAS envelope. It will contain all the days between ANC visits, so the participant can mark daily after taking the pill. The nurse will review the card at every visit and counsel accordingly.

MIA study IFAS envelopes
Envelopes containing a predetermined number of IFA pills will be issued to study participants at every scheduled visit. For the purpose of assessing adherence, women enrolling in the study will be given an extra two pills. Ordinarily, women should be given sufficient pills to last between ANC visits. It will be expected that adhering participants would return exactly two pills. The number of pills in each envelope will be blinded to the women.

Wall calendars
This will serve as a participant's reminder of the importance of antenatal IFAS, and ANC visit dates. Health workers issuing the calendar will clearly mark the ANC return dates on the calendar so the women 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 will be adapted from the national IFAS campaign materials.

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

ANC, antenatal care; IEC, information, education and communication; IFAS, iron and folic acid supplementation; MIA, maternal IFAS awareness; PRC, pill reminder card.

Table 2 Components of the MIA study intervention

Audience	Intervention
Control period	1. Current standard of care. Women are given general health education at triaging room; ANC return dates are recorded in mother–child booklet and HF appointments diary and IFAS issued at dispensing unit without any emphasis on IFAS or ANC return dates
Health workers	1. Overview of IFAS rationale, dosing schedule, pill reminder card 2. MoH flipchart with key points to use during health talks 3. MoH algorithm for counselling on antenatal IFAS
Pregnant women	1. Morning health talks on risk of anaemia 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)	1. Facility wall charts with messages on antenatal IFAS 2. Sufficient supply of IFAS 3. Monthly audits and feedback by study and county team

ANC, antenatal care; HF, health facility; IFAS, iron and folic acid supplementation; MIA, maternal IFAS awareness; MoH, Ministry of Health.

cards. Continuous uptake of IFAS will be self-reported and confirmed by probing, PRC inspection and residual pill count. Routine clinical data on fetal growth and blood haemoglobin concentrations will be used as indirect measures. The secondary outcome will be changed in IFAS knowledge and attitudes which will be measured through a cross-sectional survey in a subset of the study participants.

Sample size

The number of clusters to enrol in the trial will be determined using the following two equations proposed by Hayes and Bennett.[52] Equation 1 determines the number of individuals in each arm for individually randomised trial. This is fed into equation 2 to derive the number of clusters needed for a cluster randomised trial.

$$n = \left(z_{\alpha/2} + z_{\beta}\right)^2 \left[\frac{\pi_0\left(1-\pi_0\right)+\pi_1\left(1-\pi_1\right)}{\left(\pi_0-\pi_1\right)^2}\right] \quad (1)$$

$$c = 2 + \left(z_{\alpha/2} + z_{\beta}\right)^2 \left[\frac{\frac{\pi_0(1-\pi_0)}{n}+\frac{\pi_1(1-\pi_1)}{n}+k^2\left(\pi_0^2+\pi_1^2\right)}{\left(\pi_0-\pi_1\right)^2}\right] \quad (2)$$

Where, n=number of individuals in each arm for individually randomised trial; $z_{\alpha/2}$ and z_{β}=z score for $\alpha/2$ and β, respectively; π_0 and π_1=proportions in presence and absence of the intervention, respectively; c=number of clusters required; k=coefficient of variation between clusters in absence of intervention.

About 6% of pregnant women in Embu consume IFAS for at least 90 days.[16] This intervention aims at detecting a 50% increase in uptake of antenatal IFAS from 6% in the control period to 9% in the intervention period (ie, 0.06 and 0.09 for π_1 and π_0, respectively) at a power of 80%. Using the first equation, the minimum number of pregnant women in each study arm would be 1205. Plugging this into equation 2, and using k of 0.25 (k values for most health outcomes are often ≤0.25),[52] the minimum number of clusters required to make reasonable references about the effect of the intervention would be 9.4 clusters. To protect against prerandomisation exclusions and non-response, 12 clusters will be recruited.

The minimum number of respondents for the baseline and endline surveys will be 91 pregnant women in each cross-section survey. This sample is based on Cochran's formula[53] assuming a 5% margin of error, 6% IFAS uptake[16] and a 5% non-response rate. The number of respondents per cluster will be proportionate to cluster workload. Additionally, one staff from each department where pregnant women receive any ANC services will be

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Table 3 Summarised role of the health service providers during the study

ANC service station	MIA study-related roles
Triaging and history taking room	Initial contact group talk: Discuss the prevalence, dangers and signs of AiP, how anaemia can be prevented and treated using IFAS. The IFAS schedule, likely side effects and how to mitigate them. Importance of ANC. Issue ANC booklet to new mothers and emphasise 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 anaemia, its signs and prevention, assess and augment her knowledge on IFAS. Advise her on IFAS (schedule, importance, safety, management of potential side effects), emphasise importance of IFAS for her and unborn child, 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 erroneous entries. Remind her how to use the PRC. Issue MIA wall calendar for first visit clients, mark all clinic return dates and explain the importance of honouring the ANC visits. Resolve any challenges that the woman has on IFAS and anaemia. Update ANC register with details of the services provided to the client
Pharmacy unit/drug dispensing room	Issue IFAS and PRC. 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 visit. Orient her on how to use PRC as an aide-memoire. Update the Bin cards

AiP, anaemia in pregnancy; ANC, antenatal care; IFAS, iron and folic acid supplementation; MIA, maternal IFAS awareness.

interviewed. Some 16 key informants (county nutritionist, county nursing officer, 2 subcounty nursing officers and 12 nursing officers based at HFs) will also be interviewed.

Recruitment

All pregnant women seeking ANC services at the selected facilities between 1 June 2022 and 28 February 2023 will automatically be recruited into the study. The study will run for nine calendar months (1 month preintervention, 7 months intervention and 1 month postintervention). This effectively totals to 60 months. The preintervention period will be used for baseline data collection and customisation of intervention while the postintervention month will be used to finalise the data collection and the handover processes. The study facilities see an average of 21 new pregnant women per month, hence a minimum of 1205 participants within 60 months.

Assignment of intervention

All facilities will start the trial at the same time point and act as controls until such time as they are randomised to crossover from control to intervention. The point at which each of the 12 HFs will transition from control to intervention will be determined through simple randomisation using computer generated random numbers (generated by principal investigator) with 2 facilities

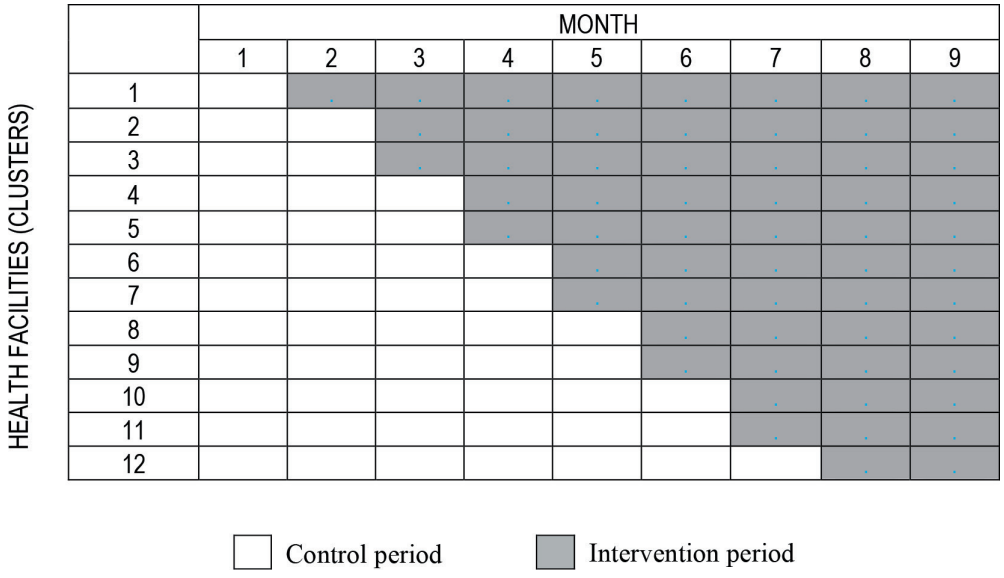

Figure 1 Diagrammatic illustration of the stepped wedge design. Unshaded cells represent data gathering in health facilities during the control period. Grey cells represent data gathering in health facilities during the intervention period.

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crossing over at a time except for the first and last months as summarised in figure 1. Facilities will be informed of the start date 1 month before the intervention to minimise contamination. The study team will activate the engagement activities (facility baseline assessment and message customisation) during this preintervention month.

Blinding

Due to the nature of the intervention, neither the participants nor health workers can be blinded to the intervention. However, names of the 12 HFs and the allocation sequence will be concealed to all except the investigators.

Data collection

Data on knowledge, attitudes and practices will be collected from patients at beginning and end of the intervention to establish sociodemographic characteristics, baseline and postintervention values. Health workers will also be interviewed at baseline to obtain contextual information to guide the customisation of the public health messages. Data on the number of women provided with IFAS and number of IFAS pills consumed, haemoglobin levels and fetal growth will be obtained from the MoH ANC register (MoH 405), IFAS bin cards and PRC. Staff in each cluster will be trained on study requirements, the data to be collected and the procedures to be followed at each ANC clinic visit. Research assistants at the clinics will be trained on how to fill the data collection forms.

To improve retention in the trial, all pregnant women will be sensitised on the importance of completing all the ANC visits. They will also be provided with a personalised wall calendar showing the ANC return dates and the services they would receive at each scheduled visit. To monitor the quality and progression of the trial monthly audits and feedbacks, and biweekly spot-checks will be conducted.

Data management

All data will be collected using open data kit forms. These include two structured questionnaires (baseline/endline assessment questionnaire for pregnant women, baseline questionnaire for health workers); a data abstraction form (for obtaining data from ANC registers, IFA bin cards and PRC for all pregnant women receiving ANC services during the intervention period); and a facility spot-check form to monitor availability of supplies and the delivery of health education sessions. The forms have been designed with checks and skips to ensure data quality at collection point. Data will be transmitted online on a daily basis and made accessible only to the investigators.

Data analysis

The intervention arm/period will be compared against the control arm. Pearson's χ^2 and paired t-test on the proportion in each pair will be used. For subgroup analysis (age, gravidae, parity, gestation at first ANC visit), regression methods will be used. Relative risk, the number needed to treat and preventable fraction will be used with corresponding 95% CIs to quantify the effect of the intervention on outcome. Analysis will include all participants and all clusters. Data will be analysed with up-to-date version of Stata. The Consolidated Standards of Reporting Trials will be followed in reporting the study findings.[54]

Patient involvement

Participants were not involved in setting the research questions or the outcome measures, but they will be involved in design and implementation of the intervention. They will also be key in disseminating findings from baseline survey which will be a critical motivator in the uptake of IFAS during and beyond the study.

Ethics and dissemination

The study has been approved by the Kenyatta University Ethical Review Committee (PKU/2443/11575), and research permit obtained from the Kenya National Commission for Science, Technology and Innovation (NACOSTI/P/22/16168). Further permission will be obtained from the Embu County health management team. Informed consent will be obtained from the pregnant women and confidentiality assured throughout.

Participating HFs will receive biweekly feedbacks during the active phase of the intervention. Findings of the trial will be widely disseminated through peer reviewed publications and presentations at conferences in order to inform future IFAS and micronutrient supplementation strategies.

Contributors HN conceptualised the study and conducted the initial review of literature. HN, EN and EK were in charge of the study design and wrote the original draft. All authors contributed to the background research, data analysis methodology and the statistics, including sample size calculations. HN and MWG were in charge of the ethics approval process. All authors contributed to the revision of the study. All authors read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer-reviewed.

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