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ORIGINAL ARTICLE

REPRODUCTIVE, FEMALE AND CHILD HEALTH

Maternal acceptability of iron supplementation in young breastfed rural Gambian infants

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Abstract

Introduction: A recent analysis of Gambian infants showed that plasma iron concentrations decline rapidly from birth to levels below the 95% reference range within 5 months of age. To address this issue, a clinical trial was initiated to assess the efficacy of early iron supplementation in breastfed infants under 6 months of age ('Iron Babies'; NCT04751994). To understand if such an intervention is feasible for scaleup, the acceptability, through the lens of local stakeholders and mothers (as the primary caregiver), must be considered.

Methods: An embedded qualitative study, therefore, explored acceptability through focus group discussions with local stakeholders and interviews with mothers. Four focus group discussions with local stakeholders ($n = 19$) and individual interviews ($n = 14$) with mothers whose infants were enrolled in the clinical trial were conducted. Qualitative data were analysed with respect to an implementation acceptability framework using Template Analysis.

Results: From the focus group discussions, there was a general sense of enthusiasm for the intervention, but also a concern due to confusion around nutritional messaging. The intervention was acceptable to mothers with limited mention of side effects and enthusiasm for participating in clinical trials on iron supplementation. However, when looking at scaleup, there were mixed opinions on the practicality of daily supplementation, as well as concerns around costs. In addition, it was suggested that proper dissemination of information and inclusion of all family members in decision-making, especially fathers, is key to acceptability.

Conclusion: There was no indication that stakeholders or mothers were resistant to iron supplementation of breastfed infants.

KEYWORDS

nutrition, qualitative research

INTRODUCTION

Iron deficiency anaemia, the largest nutritional deficiency worldwide, remains the leading cause of years lived with disabilities in low- and middle-income countries and is associated with more than 120 000 maternal deaths per year.[1] The prevalence of anaemia is five times higher in low- and middle-income countries than in high-income countries, with about 43% of children between the ages of 6–59 months being anaemic.[1,2]

Abbreviations: EBF, exclusive breastfeeding; FGDs, focus group discussions; IDIs, individual interviews; NaNA, National Nutrition Agency.

Sergio A. Silverio and Sophie E. Moore contributed equally to this study.

A recent pooled analysis of 317 rural Gambian infants found that they were born with a reasonable endowment of iron despite being born to deficient mothers.[3] However, following birth there was a rapid deterioration of markers of iron status and a simultaneous increase in markers of iron tissue demands.[3]

While efficacy studies in infants have shown that early nutrition interventions improve infant nutritional status, to examine whether such interventions can be effectively taken to scale, a better understanding of maternal acceptability is required.[4–6]

Acceptability has become a key consideration in evaluating and implementing healthcare interventions.[7] Definitions of acceptability are vague in the literature, but vary from social to treatment acceptability.[8–12] Successful implementation requires the acceptability of an intervention from both the perspective of the providers and recipients.[13,14] When an intervention is deemed acceptable, adherence is often higher, leading to improved clinical outcomes.[15,16] Additionally, providers must find an intervention acceptable to ensure it is delivered as intended, in turn increasing the effectiveness of the intervention.[17,18]

On this backdrop, the aim of the current study was to assess the acceptability of an iron supplementation efficacy trial in infants under 6 months of age in rural Gambia (efficacy trial: *Iron Babies*). The following objectives were assessed:

- To explore mothers' (as the main care providers) perspectives on the acceptability of iron supplementation in their young infants through individual interviews (IDIs).
- To explore mothers' willingness to involve their young infants in clinical trials on iron supplementation.
- To explore the acceptability of iron supplementation in young infants, under evaluation in the primary clinical trial on which this work is nested, through focus group discussions (FGDs) with local stakeholders.

To address the objectives of the study, data were analysed with respect to an implementation framework. Frameworks act as a guide to conceptualise an intervention to a specific aspect of implementation.[19] The clinical trial in which this study is embedded (*Iron Babies*) is an efficacy study; therefore, not all components of this framework are relevant to the data collected. However, it was used as a starting point.

Template analysis, as defined by Brooks et al.[20] (p. 203), 'is a form of thematic analysis which emphasise the use of hierarchical coding but balances a relatively high degree of structure in the process of analysing textual data with the flexibility to adapt it to the needs of a particular study'. Key to this technique is the use of a coding template, based on a subset of the data, which is then applied to the remaining data and revised and refined.[20] This form of analysis does not first set a sequence of coding levels, but instead lets the researcher develop themes where the richest data are found.[20] Template analysis often utilises interview transcripts, FGDs, and questionnaires.[20] It follows a methodical six-stage process: (1) data refamiliarization; (2) preliminary coding; (3) thematic organisation within the template; (4) defining the template; (5) application of template to the full data set; and (6) finalisation of template definitions.

METHODS

To assess the efficacy of early iron supplementation in infants under 6 months of age in this setting, a double-blind, placebo-controlled, randomised pilot study was conducted. To measure the impact of daily iron supplementation on serum iron concentrations, healthy, breastfed infants ($n = 101$), aged 6–10 weeks at enrolment, were randomised to receive daily iron (7.5 mg/day of iron as ferrous sulphate) or placebo drops for 98 days. The primary and secondary endpoints were serum iron, serum ferritin, haemoglobin and other haematological markers of anaemia, iron deficiency and iron deficiency anaemia after 98 days of supplementation. Full details of the *Iron Babies* trial and this qualitative adjunct study have been published in detail in the trial protocol.[21] The methods applicable to this qualitative study are provided below.

Study setting

Data collection for the current study took place in The Gambia, West Africa. The *Iron Babies* trial was based at the Jarra Soma Regional Hospital with study participants recruited from the Soma region of The Gambia through community-based clinics and birth attendants. The current study was conducted in the same community, recruiting local mothers and stakeholders.

Study design and methodology

This approach explores the effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation. Qualitative methods were used to explore the acceptability of such an intervention proposed in the *Iron Babies* trial.

The two following components compromise this qualitative study:

1. Qualitative: FGDs with local stakeholders.

Four FGDs took place with local stakeholders to inform the IDIs with infants' mothers (Supporting Information: Appendix 1):

- Members of the National Nutrition Agency (NaNA).
- *Iron Babies* trial health workers.
- Non-*Iron Babies* trial health workers.
- Mothers from surrounding villages whose infants are not enrolled in the *Iron Babies* trial.

The FGDs were audio recorded, lasting on average 1 h, and were conducted in English or Mandinka (the predominant local

language). The location was chosen by the interviewee to add comfort. Both staff from the main *Iron Babies* trial and those not working for the main trial were interviewed to ensure a wide range of opinions were sought. We aimed to recruit around five participants to each FGD, in accordance with general recommendations for focus group size in qualitative research (20 participants total).[22]

2. Qualitative: IDIs with infants' mothers.

The IDIs discussed the acceptability of iron supplementation in infancy from the perspective of mothers whose infants were enrolled in the *Iron Babies* trial. The data from the FGDs were used to finalize the interview schedules (Supporting Information: Appendix 2). Using these schedules, IDIs, not lasting longer than 1 h, were conducted in Mandinka by a qualitatively trained female member of the study team and were audio recorded. All mothers were Mandinka (the most common local tribe making up 75% of the *Iron Babies trial* participants) to provide homogeneity in the translation of the IDIs. The location was chosen by the interviewee to add comfort and included the homes of participants and within local villages. IDIs employed concurrent and retrospective data collection. Both the mothers and researchers were blinded. Maximum variation purposive sampling of the mothers whose infants were enrolled in the main study was used to ensure many opinions are represented.[23,24] We anticipated an approximate sample size of 10–20 mothers to reach data saturation.

Data collection

Before conducting FGDs and IDIs, the guides and schedules were piloted among the *Iron Babies* trial study team. Two female interviewers piloted the FGD guides on members of the *Iron Babies* trial study team and adjustments were made from the feedback. Mock IDIs were then conducted on other study team members of the *Iron Babies* trial study team. This helped to adjust the FGD guides and IDI schedules, but likewise, acted as an opportunity for the interviewers to familiarise themselves with the structure of the FGDs and IDIs.

Consent and ethics

Full written informed consent was provided by all study participants. The studies have been reviewed and approved by the applicable Scientific Coordinating Committee and Ethics Committees.

Data analysis

The FGDs and IDIs were audio recorded and later transcribed and concurrently translated (where needed) into English.

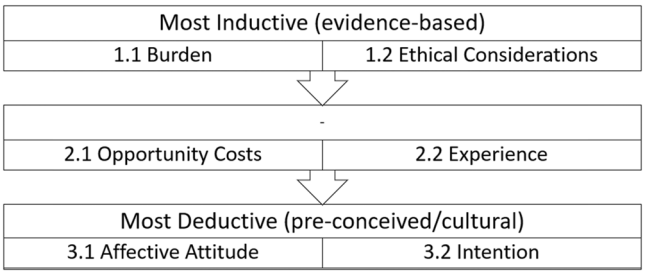

FIGURE 1 Adapted acceptability framework.

Data were analysed with respect to the implementation framework known as *Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework* using Template analysis.[7,20,25]

The six themes used to analyse the data were *burden*, *ethical consequences*, *opportunity costs*, *experience*, *affective attitude* and *intention*. The acceptability framework was adapted, and the themes were placed on a spectrum of being the most inductive or evidence-based, to the most deductive or preconceived/cultural, as well as *ethical consequences* being adapted to *ethical considerations* (Figure 1).

The qualitative data were uploaded into, managed and analysed in NVivo using Template analysis.[20,25] Data were coded to the six themes in the framework, with minor variations to make analytical sense of the data. The acceptability framework used to develop the template for analysis is a macro-level conceptual framework, which can be applied to data that consider both meso-levels (data from the FGDs) and microlevels (data from IDIs). While acknowledging the domains may not all reach saturation, these are based on an extensive search of the literature by the framework authors and have been tested in different fields, so were used as a basis for our analysis. The extent to which the framework was valuable in this study is later discussed.

This coding was conducted by one researcher and 25% of the data was independently coded by another researcher to ensure rigour of coding. Throughout the coding process, the two researchers met to discuss the codes and applicability of the acceptability framework. Any disagreements were resolved by discussion with a third researcher.

RESULTS

Qualitative data analyses

Four FGDs were conducted ($n = 19$ individuals). All participants were Gambian. Characteristics of the FGDs participants are detailed in Table 1. IDIs were conducted with mothers whose infants were enrolled in the *Iron Babies* clinical trial ($n = 14$). All mothers were Mandinka (the most common local tribe) and married. Demographic data from the IDI participants can be found in Table 1. *The Medical Research Council Unit the Gambia at the London School of Hygeine and Tropical Medicine* is referred to as 'the unit'.

TABLE 1 Demographics of the four focus group discussions ($n = 19$), and individual interviews ($n = 14$).

	Focus group discussion demographics ($n = 19$)				
	Participant ID	**Gender**	**Age (years)**	**Years working for their organisation**	**Number of children**
Members of the National Nutrition Agency	Participant 1	Male	56	21	NA
	Participant 2	Male	53	21	
	Participant 3	Female	48	21	
	Participant 4	Female	31	6	
Iron Babies trial health workers	Participant 1	Male	50	19	NA
	Participant 2	Male	51	3	
	Participant 3	Male	26	7	
	Participant 4	Male	38	8	
	Participant 5	Male	51	23	
Non-*Iron Babies trial* health workers	Participant 1	Female	29	6	NA
	Participant 2	Female	19	1	
	Participant 3	Female	39	14	
	Participant 4	Female	19	1	
Mothers from surrounding villages whose infants were not enrolled in the *Iron Babies* trial	Participant 1	Female	24	NA	4
	Participant 2	Female	28		3
	Participant 3	Female	24		1
	Participant 4	Female	35		5
	Participant 5	Female	36		7
	Participant 6	Female	37		3

	Individual interview demographics ($n = 14$)				
	Age (years)	**Number of children**	**Location of births**	**Educational attainment**	**Employment**
Participant 1	40	6	Hospital	None	Cook
Participant 2	27	2	Health centre	Primary	Housewife
Participant 3	40	5	Health centre	None	Housewife
Participant 4	24	3	Hospital	Primary	Housewife
Participant 5	28	3	Home (1) and hospital (2)	Primary	Housewife
Participant 6	28	7	Hospital	Secondary	Housewife
Participant 7	28	4	Hospital	Primary	Housewife
Participant 8	23	2	Hospital	Secondary	Housewife
Participant 9	20	3	Hospital	Primary	Housewife
Participant 10	19	1	Hospital	Secondary	Housewife
Participant 11	26	1	Hospital	Secondary	Housewife
Participant 12	25	4	Hospital	None	Housewife
Participant 13	30	6	Home (2) and hospital (4)	None	Cleaner
Participant 14	30	5	Hospital	Primary	Housewife

Abbreviation: NA, not applicable.

Template analysis

The below findings are based on the constructs of the acceptability framework,[7] which was used as a template for analysis. Illustrative quotes and analysis were separated by FGD (Tables 2–4) and IDI for each of the six themes.

Illustrative quotes are presented using the following nomenclature:

- NaNA: NaNA FGD-PX (where PX indicates participant number, i.e., P1).
- *Iron Babies* trial health workers: IB FGD-PX.
- Non-*Iron Babies* trial health workers: N-IB FGD-PX.
- Mothers from surrounding villages whose infants were not enrolled in the *Iron Babies* trial: M FGD-PX.
- IDIs: IDI-PX.

Burden

Burden is the burden (when not financial) of being involved in the clinical trial or supplementing infants. Burden was categorised as the most inductive, along with ethical considerations.

From the FGDs, burden was frequently perceived as the mothers struggling to give the supplement to their infant in a real-world setting. However, not all participants

TABLE 2 Illustrative quotes from the focus group discussions with local stakeholders for Theme 1.

1.1 Burden	'They [mothers] will not be able to give their infants [supplements] as regularly as the field assistant, because this is their jobs…because they monitor everything and make sure the supplements are given to the child'. (N-IB FGD-P1)
	'The fathers should be included in this discussion, because maybe at times the mothers might forget [to give the supplement]…but if the two of them are informed at the same time, if one forgets the other will not'. (N-IB FGD-P2)
	'We are capable of giving it [supplements] to them'. (M FGD-P2)
	'Make a community sensitisation first…but other family members who aren't present…some of them would say they don't want to participate…and start complaining. Just have the patience, explain it to them and what the study is and the benefits that this iron supplement is going to give to the infants'. (N-IB FGD-P1)
	'Most of the mothers…understand by explaining to them what they have not learnt at school…it may change some of those mothers' [minds about enroling]'. (IB FGD-P5)
	'Because they will ask you "if anything happens, are you going to take us to the unit?"…The family may say, "we are in the project". What would they expect from you? Like if somebody falls sick what will happen?' (IB FGD-P5)
	'NaNA with the support of the communities, created those [antenatal education] groups…We are in…over 1,000 communities in The Gambia…The Gambia has about 2,000 settlements. So almost we are in half of the country…We frequently talk to mothers, educate them. Anaemia is one thing we educate these mothers on'. (NaNA FGD-P3)
1.2 Ethical considerations	'Why is the unit collecting blood from babies…I heard that they are collecting blood and selling it'. (N-IB FGD-P3)
	'It's also important to tell them [families] how many times you will be taking the blood of their babies because they are very sensitive about that…That may discourage many participants. To want to remove from the study'. (N-IB FGD-P4)
	'Some of the participants will ask about the safety of the iron…Is it going to cause harm to their infants?…Talk about the iron supplements given to the child, that will just break the barriers…Like telling the mothers that this iron is a medicine'. (N-IB FGD-P1)
	'Once we start supplementing the child…they will have iron in their systems which we know iron is a good medium for the growth of bacteria…The most common infections, childhood infections here, malaria is one of course, but you also have diarrhoea diseases, pneumonia, these could be bacterial infections as well'. (NaNA FGD-P1)
	'In The Gambia a lot of women still die as a result of anaemia. So they are not taking the iron tablets just to build up their stores for their babies, but it's to protect themselves…So the messaging should be in such a way that there is a link between the iron in the mother and the iron in the child'. (NaNA FGD-1)
	'Giving the infants the supplements now, can it discourage the mothers from taking [iron themselves]? That can be also another un-intended consequence…there are issues mothers complain of…constipation, taking different excuses as to why they were not taking it'. (NaNA FGD-P4)
	'If you explain to the mother, they will understand [why this supplement is important]…We are talking about medicine'. (IB FGD-P1)
	'They [mothers] would be worried because this is the norm, exclusive breastfeeding is everywhere. One the news, on the television…We are told to not even give a drop of water to the kids. Now comes a study that is telling you…we will be giving an iron supplement to your baby daily…We won't be comfortable taking it'. (IB FGD-P3)

Abbreviations: FGD, focus group discussions; NaNA, National Nutrition Agency.

TABLE 3 Illustrative quotes from the focus group discussions with local stakeholders for Theme 2.

2.1 Opportunity Costs	No data were present in FGDs for this subtheme.
2.2 Experience	'These messages have been given to them [communities] at the right time by the right people…We have that trust…between them and their community structures. And they believe in what they told them previously, they have seen benefits in that'. (NaNA FGD-P2)
	'Mothers will have questions…and their questions are relevant…Let's make sure that whenever they need clarification, they get that clarification…from the right person'. (NaNA FGD-P4)
	'If the feedback [trial result] is not given, people are discouraged. You just come here, do your business, get your profit. But you just leave. Whether they are healthy or not healthy, they have no information'. (IB FGD-P5)
	'I will thank and praise them [the unit] for the wonderful work they are doing… We don't have to buy medicine, we are given it free of charge'. (M FGD-P6)

Abbreviations: FGD, focus group discussions; NaNA, National Nutrition Agency.

TABLE 4 Illustrative quotes from the focus group discussions with local stakeholders for Theme 3.

3.1 Affective Attitude	'The mothers…will ask:…"why is my infant taking supplementation at this early stage of six weeks?" And other family members too might intervene:…"why is the unit doing such and such…why is your child taking these supplements? Is your child sick? What is the problem?"' (N-IB FGD-P1)
	'The immediate benefit of the study. Most [families] are almost always concerned with that…They will be asking, "I have been giving you my child's blood, still now, I don't see anything".' (N-IB FGD-P2)
	'All the mothers are aware of not giving even a drop [of water] to their babies because of the health implications of giving that…It is very important if we are going to give iron…it doesn't mean that you can give the child water. They need to understand this is a health routine'. (IB FGD-P2)
	'"Now they are telling us, our babies from six weeks can take these drops". So it [the trial] has to go with education that will clarify the issues to these mothers'. (NaNA FGD-P3)
3.2 Intention	'Their in laws [may say]: "I have not given that [iron] to all my children and they have all grown well"…During the consenting, if the in laws were present, call them and explain everything to them…Acceptability is very crucial in this'. (N-IB FGD-P1)
	'They have village health workers. People who are there to lead, the Alkali or the head…So you have a meeting with those close people, so they can disseminate [information]…that will also help…And the field workers…they should also have a clear understanding, or knowledge about what is the importance of this iron…If you cannot answer it [the questions] they will say he or she is here giving my child medicine and…does not even know the benefit…or the importance of the medicines'. (N-IB FGD-P4)
	'The messaging should be consistent…uniform…But once the messaging starts to be disjointed, the acceptability starts to be a problem…To be successful, obviously the fathers are the key decision makers, but the in-laws, the grandparents of the lady, are very key in making decisions…Childcare is shared within the household, lots of people are involved with care of the child in the household'. (NaNA FGD-P1)

Abbreviations: FGD, focus group discussions; NaNA, National Nutrition Agency.

anticipated this as a burden. Additionally, study enrolment and community sensitisation were perceived as a sensitive issue and must be approached correctly and with patience. Likewise, education levels were noted as important to consider when sensitising the community so participants can have a clear understanding of the purpose of the study. When enrolled in a clinical trial, a participants' full health needs are covered by the study, regardless of whether it is linked to the intervention or not. This level of care was noted as then being expected by other family members and potentially posing a burden on the trial. Illustrative quotes can be found in Table 2.

When not involved in trials, access to proper medical care in The Gambia was noted as reccurring burden in the maternal IDIs.

> Sometimes they give me medicines and other times, I will be asked to go and buy it at the pharmacy because not all the medicines are available [at the hospital]…When there are many patients it takes a long time to get treatment. (IDI-P13)

Additionally, when not involved in trials, access to transportation can pose a burden.

> It's difficult to get transportation. Even when I was about to deliver my infant, I walked to the hospital. (IDI-P2)

As with the FGDs, mixed opinions about the act of supplementing infants in the real-world setting were raised in

the IDIs. From issues with the infant accepting the drops to mothers remembering to administer the supplement.

> I will forget sometimes…I will be needing their [health workers] assistance. (IDI-P8)

> We sometimes struggle just to have the infant take it…but once it's in his mouth, he takes it easily. (IDI-P11)

Ethical considerations

Ethical considerations are the associated side effects of the intervention. Ethical considerations were categorised as the most inductive, along with the burden.

Ethical considerations were more frequently noted in the FGDs than the IDIs, despite none of the FGD participants being enrolled in the study. A common reoccurring theme was the dislike of providing blood samples for research and concerns about selling participant's blood. Additionally, subsequent side effects around the supplementation were expressed as a concern for mothers. Therefore, it was noted that ensuring adequate community sensitisation and addressing all concerns are important for easing any hesitations around the intervention. Antenatal care guidelines in The Gambia include the provision of iron and folic acid. However, members of NaNA commented on the associated side effects of iron, causing compliance issues, so if policy changes to recommend young infants to also take iron, it was believed that this may further complicate noncompliance in mothers, therefore exacerbating the problem of antenatal iron deficiency. Lastly, proper dissemination of information was noted as crucial to decrease this potential issue. NaNA endorse the World Health Organisation policy of exclusive breastfeeding (EBF) to 6 months of age, and this is promoted through their Baby Friendly Hospital Initiative. EBF in infants under 6 months of age is common, so NaNA mentioned it is important to ensure mothers understand why the study is giving iron, a medicine, during this period of EBF.[26] Illustrative quotes can be found in Table 2.

The issue of side effects during the intervention only came up a few times in the IDIs, however, like in the FGDs, the issue of blood samples when participating in clinical trials was noted.

> What scares people away from the unit…the little blood that they take from people. That is what they say: "the unit takes people's blood". (IDI-P1)

Opportunity costs

Opportunity costs are those that influence adherence and trial participation. Given this was an efficacy study, opportunity costs were often hypothetical. It was considered both inductive and deductive. Opportunity costs were not noted in the FGDs; however, it was a common theme in maternal IDIs.

When mothers were asked in IDIs about the affordability of supplements and if they could afford iron supplements in a nonclinical trial setting, the issue of cost was continuously noted.

> It would be difficult for me…Our income is dependent on fishing and at times my husband does not have any fish, hence no money in the household. (IDI-P4)

> It will be hard for me as medicine is very expensive nowadays. (IDI-P8)

Experience

Experience is the perception, and satisfaction with the intervention. It was considered in the middle of both inductive and deductive.

Within FGDs, community and individual sensitization before study initiation was considered a critical element of ensuring study success. Further, it was stated that failure to disseminate study results on completion can have a negative effect on participant's experience. However, when enquiring with the mothers about their past experiences with studies, the responses were all positive. Illustrative quotes can be found in Table 3.

Mothers from the IDIs had positive experiences with their participation in the clinical trial and often praised the unit for their work and the healthcare they provided. Most noted was the quality of care that was given if an infant ever had adverse events.

> Since they started giving the medicine [daily drops], I haven't seen any negative effects… The medicine has helped my infant to gain weight…Even when your infant got sick in the night they came and checked to know what happened…They will give you medicine, but when it's something serious they will take both of you [to the health facility and]…they will drive you back home. (IDI-P2)

> Since I joined the study, my infant has not been having fever and all those health issues…I must thank the unit for their support because after my infant fell ill without my knowledge, we were taken to Keneba to get admitted and later referred to Fajara, where we spent more than two weeks treating my infant and during these periods everything was free for us including food…If not for the unit it would have been difficult for me…I cannot ever pay for what the unit gave me, because without them my infant would have died. (IDI-P4)

> I am very happy…I have noticed many positive changes in my infant's health…It has turned my infant into a much stronger and healthier infant because I have seen the difference between him and other infants that didn't take it…both mentally and physically. (IDI-P12)

Mothers not only reflected on their experience of the intervention but also breastfeeding. Specifically, the importance of breastfeeding was noted, especially EBF until 6 months of age as well as the daily drops causing the infant to feed better.

> It is very important because since my infant was born, I didn't give her water yet, all I give her is breastmilk…Some people were saying she is premature due to her size, but I kept on breastfeeding her and I didn't leave too much of a gap between the next feeding…She is much stronger compared to before…The more she drinks the medicine [daily drops] the more she breastfeeds too. (IDI-P2)

> The medicine [daily drops] can even help the infant to eat more. You know if you are not healthy you won't be able to breastfeed as well, so the medicine will help to keep the infant healthier. (IDI-P5)

Affective attitude

Affective attitude is reported as mothers' attitudes once the trial had been initiated or hypothetically for the FGDs. It was categorised as the most deductive, along with intention.

In the FGDs, issues were raised around the varying attitudes in the communities towards the intervention, and how this may affect participation in the trial. A noted theme was the desire to see immediate impacts from an intervention. Additionally, it was suggested that the iron supplementation could cause confusion around the need for continuous EBF and that to correct this issue, education around the intervention is key. Illustrative quotes can be found in Table 4.

However, in the IDIs, mothers seemed enthusiastic about the offer to have an intervention that may benefit their infant's health and were very happy with the treatment they received during the study.

> The unit, the way they work is what satisfies me. And how they handle people if they are sick. It is civilised that's why. I know they will not do any harm to the infant. Everything they do will be towards the health of the infant, that's what I admire. (IDI-P2)

> I am very impressed with the work of this study, because they have the interest of their patients at heart and are ready to help anytime they are needed or called…I encouraged anyone that wants to join to join because their medicine [daily drops] is very good for infant and…it is for the betterment of your infant. (IDI-P11)

Intention

Intention was mothers' intention to join the study or hypothetically for the FGDs. It was categorised as the most deductive, along with affective attitude.

It was noted in FGDs that mothers may find the guidance of giving iron supplements during the period of EBF confusing, but to help mothers be more inclined to be involved in a study, sensitisation and information sharing were important. Additionally, it was stressed that the sharing of information must be done through culturally accepted channels such as village heads and local stakeholders. Illustrative quotes can be found in Table 4.

In the IDIs, mothers expressed their desire to be involved in the study, because they knew it could enhance their infant's access to healthcare. Sometimes this even meant disregarding concerns other mothers had expressed about clinical trials. Often noted was the need for their husbands to give permission for the infant to join the study.

> I said "ah my infant won't join the unit, because I hear that they say the unit used to take people's blood". When my husband came…he said, "take the infant to the unit, don't you know that the unit takes more care than these other hospitals…when your infant is sick, they will come up to your house to attend to your infant". (IDI-P5)

> I have seen that their work was very good, they give help to people and there are good results in the health of the infants…I joined it willingly after consulting my husband, who also agreed to it…to maintain my infant's good health. (IDI-P7)

DISCUSSION

Overall, there was no indication that stakeholders or mothers were resistant to iron supplementation of breastfed infants. The FGDs indicated a general sense of enthusiasm for the intervention, but also a concern due to confusion around nutritional messaging. However, the intervention was acceptable to mothers with limited mention of side effects and enthusiasm for participating in clinical trials on iron supplementation. Key to acceptability is the proper dissemination of information and inclusion of all family members in decision-making, especially fathers. When

considering scaleup there were mixed opinions on the practicality of daily supplementation, as well as concerns around costs.

IDIs

The IDIs explored maternal acceptability of iron supplementation in infants on the microlevel. Significant burdens among the Gambian population were indicated to be access to healthcare and transportation to hospitals and health centres. It was often noted that outside of the trial, prescription medicine needed to be paid for, which was a financial burden. While the answers were varied, some mothers did flag that supplementing the infants themselves in a real-world setting may be a burden due to other commitments or forgetting. A qualitative study conducted in The Gambia looking at issues around care found that a main barrier to getting the necessary treatment was associated transport costs.[27] A meta-analysis of iron and folic acid supplements in Ethiopian women found forgetfulness to be a major barrier to adherence.[28]

For ethical considerations, side effects were rarely noted, and when they were it was in the context of how helpful the trial was in responding and providing healthcare for these incidences. No mother saw the side effects as negative or due to the intervention itself. The issue around fear of blood sample collection was raised as there are concerns about what happens with the blood once it is drawn and some confusion that the research unit may sell blood. A study looking at the misconceptions around blood samples and its impacts on trial participation in a village in rural Gambia found that originally finger-pricking posed no problem, but as soon as 'rumours' about the use of the blood and concerns around the health implications of blood loss started to spread, recruitment rates suffered.[29]

Some mothers were also worried about the cost of purchasing the iron if it was for sale in the future. This has been seen in the past in The Gambia with barriers to healthcare due to related costs.[30]

Maternal experiences were very positive when describing the daily drops as bringing them '*happiness*' and being '*very good*'. Mothers also appreciated the ability to be able to call the team at any time if there was a health issue with their infant, noting prompt free care and transportation, if needed. A previous qualitative study in The Gambia also found this increase in healthcare to be the main facilitator in an iron supplementation trial in children.[31] Some mothers even noted physical health increases in their infants such as weight gain, getting 'stronger' and less sicknesses. It was believed that the supplements helped the infants breastfed more effectively, which made mothers happy due to breastfeeding being beneficial for the infant.

Again, like with experiences, mothers' affective attitudes towards the intervention were positive. Mothers often noted that if someone wants to help you in the healthcare of your infant, and at no cost, why would one reject such help, especially in a setting such as The Gambia where access to and affordability of healthcare was as a noted burden. The care given to the infants in *the clinical trail* was described in a positive light, encouraging some mothers to express that they would never want to quit such an intervention. The desire to be involved in additional trials was expressed. These experiences are reflective of other qualitative literature looking at the barriers, facilitators, and benefits of an iron supplementation trial in children in The Gambia.[31]

Lastly, maternal enthusiasm to join the study was high. Like their affective attitude, mothers mentioned that the study would enhance their infant's health and if someone made such an offer, of course, they would take it. The issue around blood sample collection was noted, but that this was not a problem in deterring them from joining the study. The mothers also highlighted how crucial the father of the infant was in making the final decision for the infant's healthcare and needs. A study looking at participant retention in sub-Saharan Africa found that consent withdrawal due to the father not being involved at the point of consenting or parents no longer being comfortable with blood samples were the main reasons for not completing the trial.[32]

FGDs

The FGDs explored the acceptability of iron supplementation in young infants with local stakeholders at the meso-level. Multiple burdens were raised in the FGDs. For example, there were concerns around supplementing infants in a real-world setting, although not all agreed this would be a burden. It was noted that community sensitisation would be difficult as other family members may get involved with negative opinions, so it is crucial to be clear and consider education levels when doing so. Additionally, it must be made apparent that there would be no remuneration for joining the study, as other family members may ask how they would benefit. A previous study in The Gambia concluded that to overcome these burdens one must better inform and educate the participants and their caregivers.[29]

In terms of ethical considerations, there may be confusion around the acceptability of supplementing infants during EBF. As mentioned in the NaNA FGD, there have been noncompliance issues with mothers taking iron and folic acid in The Gambia, so making it clear that mothers must still take this even if infants are supplemented, as well as the potential side effects infants may experience, must be well explained. These considerations can be managed through proper sensitisation within the communities. To facilitate clinical trials, health education has been found to be crucial to avoid misconceptions in The Gambia.[27]

Maternal experience was perceived as positive by the FGDs, noting that with the right people being involved in sensitisation and answering all mothers' questions, they would be happy. An issue in the past was that study findings were not always disseminated to the community, so to ensure a positive experience, it was noted that findings

should be shared with the local communities. From the maternal FGD, those who had past experience in trials were all positive. In the literature, a fundamental feature of community-based research is engaging with community members and disseminating the research findings.[33]

Affective attitudes were influenced by other family members intervening, mothers wanting to see immediate benefits to their infants, and confusion around the ability to give iron during EBF. Again, it was mentioned that it was important to include husbands in these discussions and educate the potential participants on the reason for the intervention.

Intention may be inhibited by the confusion around the acceptability of giving iron during the period of EBF. It was noted as vital that information is shared through socially accepted channels and respects cultural hierarchies. In The Gambia, childcare was highlighted as a household decision, not just that of the mother. So informing the communities of the intervention through key stakeholders such as the community health workers, the village and compound head, in-laws and especially fathers were seen as crucial. Likewise, it was highlighted that to ensure families are willing to join a study, the messaging is consistent around the purpose of the intervention. Community sensitisation, allowing information to be passed through the appropriate hierarchy in villages in The Gambia, has been successful in the past.[34]

Strengths and limitations

This study involved a wide array of stakeholders from mothers as the primary caregivers, to local field staff, to nutrition-focused government workers. This helps strengthen the growing body of implementation research needed for scale-up of clinical interventions, of which more is needed in low- and middle-income countries. In implementation studies, it is crucial to take a special interest in the user of the research, not just the outcomes, as well as involving a diverse array of key stakeholders.[35]

Efforts were made to increase the comfort and reduce any power dynamic in the IDIs by having a young local female trained in qualitative interview practices conduct the interviews and in a chosen location by the participant. However, the interviewer was an employee of the research unit; therefore, answers from mothers may be slightly biased as praise for the unit was often expressed. A study in Zambia, South Africa, and Kenya emphasises the importance of matching the interviewer with the participant by age, sex, and native language to provide comfort for the participants.[36]

Another limitation of this study is that it may be hard to translate to other settings. The research unit has been working in The Gambia for over 70 years, so the communities are more familiar with clinical trials.

Lastly, given that the main study was an efficacy trial, it was not possible to assess the full implementation and scale-up of such a trial in a real-world setting.

Applicability of the acceptability framework and future directions

Overall, the framework was useful for categorising the data into six main themes. However, the division of an inductive and deductive arm was not applicable. Instead, the data were interpreted to be on a spectrum of inductive to deductive, and the framework was therefore adapted accordingly. Additionally, some of the themes were felt to overlap as data could often be coded to more than one of the themes. The issue around blood samples was ethical, but also impacted intention. The issue of advising to give a supplement during the window of EBF and how this may cause confusion was an ethical consideration, but also affected intention, and fell under affective attitude. EBF also came up in experience during mothers' reflections. The need for proper sensitisation was also reoccurring in all themes apart from opportunity costs. The struggles experienced with sensitisation were raised as burdens in the FGDs. Iron supplements can cause side effects, which is an ethical consideration, and the need for proper sensitisation here was noted. In terms of improving mothers' experiences, proper sensitisation was also noted in the FGDs. Likewise, in the FGDs, the affective attitude was noted as being influenced by confusion around the intervention, which can be fixed with proper sensitisation and being sure all key community stakeholders, especially fathers, are involved. Lastly, for intention, proper sensitisation and the need for the father's consent greatly influenced if mothers wanted to be involved. Issues around the act of supplementing came up in opportunity costs, due to financial struggles, but also appeared as a burden as some mothers found they would struggle to remember and self-administer the drops in a real-world setting. A noted burden, when not enrolled in trials with the research unit, was transportation and access to proper healthcare in The Gambia, this came up in intention, affective attitude and experience as many mothers wanted to join the study for better access to healthcare and transport. They also found this enhanced their experience and improved their attitude towards the intervention. Lastly, the mother's gratitude towards the research unit and the intervention was apparent in her affective attitudes and experiences. While it was apparent that the framework covered all aspects of local stakeholder and maternal acceptability, the frequent overlap between themes implies it may help to view the framework as a continuum (Figure 1). This revised framework allows the researcher to look at the data as a continuum, as healthcare research is often complex and multifaceted. Additionally, this framework does not group findings as either inductive or deductive, because in cultural contexts such as The Gambia, views are often to some extent both inductive and deductive. This revised framework should facilitate future healthcare research around acceptability.

CONCLUSION

Overall, at the micro-level, the intervention was found to be acceptable, with limited mention of side effects or concerns around the intervention or participation in the clinical trial. However, when looking at the scale-up to the real-world setting, there were mixed opinions on the burden of daily supplementation, as well as concern around the cost of the iron. At the meso-level, there was excitement about this new intervention, but also concern over the acceptability of the intervention due to confusion around nutritional messaging. Noted as central to ensuring the acceptability of an intervention was the need for proper dissemination of information and inclusion of all family members, especially fathers, in decision-making. This study provides insight into factors central to the acceptability of nutritional interventions in young infants. Given there was no indication that stakeholders or mothers were resistant to the intervention, this data support further effectiveness trials of targeted iron in this age group.

AUTHOR CONTRIBUTIONS

This study was conceptualised by Sophie E. Moore, Isabella Stelle and Sergio A. Silverio. Isabella Stelle and Sergio A. Silverio formulated the study design. Isabella Stelle was responsible for conducting and managing the study, along with the help of Mamadou Bah and Saidykhan. Isabella Stelle carried out data analysis with 25% of data being analysed by Sergio A. SilverioS to ensure rigour. Any disputes were mediated by Sophie E. Moore. Carla Cerami is the PI on the parent study in which this study was imbedded. Data synthesis was carried out by Isabella Stelle. Isabella Stelle wrote the first draft of this manuscript. Final drafts were edited and approved by all authors. Sophie E. Moore and Sergio A. Silverio are joint senior authors.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy.

ETHICS STATEMENT

The study was conducted in accordance with the principles set forth in the ICH Harmonised Tripartite Guideline for Good Clinical Practice and the Declaration of Helsinki in its current version, whichever affords greater protection to the participants. The studies have been reviewed by the MRCG@LSHTM Scientific Coordinating Committee, The Gambian Government/MRC Unit The Gambia Joint Ethics Committee, the Ethics Committee at LSHTM, and the Ethics Committee at King's College London. Amendments went through the same process, and as necessary, changes were communicated with investigators, trial participants and registries, journals and regulators.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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