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# “Eating under protocol”: Acceptability of controlled feeding and vitamin B12 supplementation among pregnant women in Tanzania: a phenomenological qualitative study

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# Abstract

## Background

Controlled feeding interventions are widely used to assess nutritional effects; however, their success depends not only on biomedical efficacy but also on participant acceptability. In low-resource settings, limited attention has been given to how pregnant women experience such interventions within their social and cultural contexts. This study explored the acceptability and lived experiences of a controlled feeding intervention embedded within a vitamin B12 supplementation trial among pregnant women in Bagamoyo, Tanzania.

## Methods

This was phenomenological qualitative research design to explore and describe the lived experiences of participants involved in a controlled feeding clinical trial. Data was collected using in-depth interviews (IDIs), focus group discussions (FGDs), and key informant interviews (KIIs) with study participants and clinical trial staff. Data were analysed thematically using the Theoretical Framework of Acceptability (TFA), encompassing affective attitude, intervention coherence, perceived effectiveness, burden, opportunity costs, ethicality, and self-efficacy.

## Results

Acceptability was dynamic and evolved over time through participants' interaction with the intervention and its context. Positive emotional responses were shaped by supportive care and perceived safety, while improved understanding strengthened trust and engagement. Perceived health and nutritional benefits reinforced adherence. However, participants experienced challenges related to dietary restrictions, residential facility stays, and opportunity costs, including family and economic responsibilities. Cultural beliefs influenced early perceptions but diminished with ongoing clarification and positive experiences. Peer support, staff engagement, and experiential learning enhanced participants' confidence to adapt and remain committed.

## Conclusions

Acceptability of controlled feeding and supplementation interventions is shaped by interconnected emotional, cognitive, and contextual factors that evolve during participation. Designing interventions that prioritise participant support, continuous engagement, and contextual responsiveness is essential for improving feasibility and sustained participation. Integrating acceptability into maternal nutrition research can enhance both implementation and outcomes in similar low-resource settings.

## Trial registration

This qualitative study was embedded within a clinical trial registered at ClinicalTrials.gov (identifier NCT05426395) on 16 June 2022.

# Introduction

Controlled feeding trials are considered the gold standard for investigating nutrient metabolism and dietary effects due to their ability to minimise confounding dietary variability [1,2]. Such designs are particularly important in nutritional science, where intake measurement error, food insecurity, and variable dietary practices can substantially affect the interpretation of intervention effects [3]. In pregnancy, controlled feeding studies provide a unique opportunity to generate high-quality evidence on nutrient requirements, metabolism, and physiological adaptations during gestation [4].

Vitamin B12 is an essential water-soluble micronutrient involved in DNA synthesis, red blood cell formation, neurological function, and one-carbon metabolism [5–7]. During pregnancy, adequate vitamin B12 status is critical for placental function, foetal growth, neurodevelopment, and maternal wellbeing [7–9]. Emerging evidence suggests that inadequate maternal vitamin B12 status may be associated with adverse outcomes, including foetal growth restriction, neural tube defects, and poor infant vitamin B12 stores [10], while supplementation during pregnancy may improve longer-term maternal and child health outcomes [11].

Despite the scientific strengths of controlled feeding studies, their implementation can impose substantial physical, emotional, and social demands on participants [12,13]. Such studies often require strict dietary adherence, prolonged residence in research facilities, repeated biological sampling, and temporary disruption of daily routines [14]. For pregnant women, these demands may intersect with pregnancy-related discomfort, family responsibilities, childcare obligations, work-related constraints, and concerns about safety and autonomy [15]. Acceptability of such interventions is therefore not only an ethical consideration but also central to participant retention, adherence, and the validity of trial outcomes [16–18]. Qualitative research has consistently shown that participant perceptions of burden, trust, flexibility, and interpersonal support influence engagement in health interventions and clinical trials [19,20].

These challenges may be amplified in low- and middle-income countries (LMICs), where structural constraints, gender norms, mobility limitations, and competing household priorities can shape research participation [21–23]. Pregnant women in sub-Saharan Africa may face additional barriers related to transport, informal work, caregiving expectations, and limited household decision-making; however, respectful care, trust in research institutions, perceived benefits, and culturally sensitive engagement can facilitate participation [24,25]. As global calls increase for more equitable inclusion of pregnant women in clinical research, understanding participant experience has become increasingly important for ethical trial design and implementation.

Existing literature on pregnancy nutrition trials has largely focused on biological efficacy, pharmacokinetics, and clinical outcomes, with relatively limited attention to the lived experiences and acceptability of intensive dietary interventions [26–30]. This gap is especially pronounced for controlled

feeding trials in sub-Saharan Africa, where such studies are uncommon due to logistical complexity, cost, and contextual barriers. To our knowledge, the maternal vitamin B12 trial in Bagamoyo represents one of the first controlled feeding studies conducted in this region, providing a rare opportunity to examine not only nutritional outcomes but also participant experiences in a highly structured research environment.

Beyond biomedical efficacy, understanding how participants perceive food quality, meal routines, dietary restrictions, residential facility stays, and the broader social meaning of trial participation is essential for assessing the acceptability and feasibility of controlled feeding interventions. Such interventions are not solely nutritional exposures but also social experiences that shape participants' comfort, satisfaction, autonomy, and ability to adhere to study procedures. Exploring participants' preferences, challenges, and adaptive strategies can provide valuable insights into factors that influence engagement, retention, and overall intervention success. This evidence is important for informing the design of future maternal nutrition studies and ensuring that interventions are both scientifically rigorous and responsive to participants' needs and lived realities.

This study therefore aimed to explore the acceptability and lived experiences of a controlled feeding intervention embedded within a vitamin B12 supplementation trial among pregnant women in Bagamoyo, Tanzania. Specifically, it examined participants' experiences of dietary control, residential facility-based participation, interpersonal interactions with study staff, perceived benefits and challenges, and the broader social implications of trial involvement. Findings from this study are intended to inform the design, implementation, and ethical conduct of future controlled feeding and maternal nutrition trials in similar low-resource settings.

## Methods

# Study design

This study employed a phenomenological qualitative research design to explore and describe the lived experiences of participants involved in a controlled feeding clinical trial [31]. The approach focused on understanding participants' perceptions, feelings, and interpretations of their involvement, while bracketing researcher assumptions to capture authentic experiences [32].

## Study setting

The qualitative study was conducted at the Kingani Clinical Trial Facility of the Ifakara Health Institute, located in the Bagamoyo study area, Tanzania. This facility served as the site for the primary Phase I clinical trial of vitamin B12 supplementation, conducted between June 4, 2023 and March 15, 2024.

The parent trial was a single-blinded, stratified, dose-ranging study involving both pregnant and non-pregnant participants. Pregnant participants were sequentially assigned to one of three ascending dose

levels (2.6 mcg, 10 mcg, and 50 mcg), based on their baseline vitamin B12 status and dosing frequency (every 12 or 24 hours). In contrast, non-pregnant participants received only the lowest dose administered once daily.

The trial lasted four weeks, during which participants remained as inpatients at the facility to ensure controlled feeding conditions and direct observation of vitamin B12 supplementation. Additionally, pregnant participants attended one follow-up visit approximately six weeks postpartum [4].

## Theoretical Framework

This study was informed by the Theoretical Framework of Acceptability (TFA), which conceptualises acceptability as a multi-dimensional construct reflecting the extent to which individuals delivering or receiving an intervention consider it to be appropriate, based on their cognitive and emotional responses [33,34]. The framework comprises seven interrelated constructs, as shown in Graph 1.

*Graph 1: The theoretical framework of acceptability (adapted from Paynter et al., 2023; and author's innovation)* [35]

This framework provided a useful lens for exploring how pregnant women and study staff experienced in the controlled feeding intervention, including perceptions of food quality, dietary restrictions, facility-based stay, social support, and perceived health benefits [36]. It also enabled examination of broader contextual factors influencing participation, such as family responsibilities, household obligations, and trust in the research team [37]. While the study employed a phenomenological design to capture lived experiences, the framework of acceptability guided the interpretation of participants' accounts and helped situate the findings within broader implementation and maternal nutrition research.

## Participants

The study population comprised pregnant women between 25 and 28 weeks of gestation who were enrolled in the controlled feeding trial. This gestational window was deliberately selected to ensure that participants could complete the inpatient phase of the study prior to delivery while also accounting for the increased risk of preterm birth from approximately 32 weeks of gestation. Accordingly, the upper limit for enrolment was set at 28 weeks.

Trial staff directly involved in the implementation of the controlled feeding study were also included to provide complementary perspectives on study procedures and participant engagement.

## Sampling strategy

A purposive sampling strategy was employed to identify participants from the trial register [38]. This approach enabled the deliberate selection of individuals with direct experience of the phenomenon under investigation, thereby enhancing the depth and relevance of the data [39].

A purposive subsample of mothers and trial staff (clinicians, pharmacists, nurses, and metabolic kitchen officers) were selected to participate in in-depth interviews (IDIs) and focus group discussions (FGDs) [40–42]. Selection criteria included level of participation in the controlled feeding study and ability to provide detailed experiential accounts. Sampling continued until sufficient depth and diversity of perspectives were achieved [42]. However, the sample of a total of 24 participants was included in the qualitative study, comprising 7 in-depth interview (IDI) participants, 5 key informants (KIIs), and 12 focus group discussion (FGD) participants.

# Controlled feeding intervention

Participants received standardised meals tailored to the study protocol [4], alongside daily vitamin B12 supplementation at varying doses. All meals were consumed within the facility under supervision to ensure adherence and protocol compliance during the four-week inpatient phase.

## Data collection

Data were collected using semi-structured IDI, KII, and FGD guides developed specifically for this study. The guides were informed by the study objectives, the Theoretical Framework of Acceptability (TFA), and relevant literature on controlled feeding interventions and qualitative research. They were designed to ensure consistency across interviews while allowing sufficient flexibility to explore participants' lived experiences, meanings, and probe emerging themes [43,44]. The English-language interview guides are provided as **Additional file 1**.

Interviews and discussions were conducted in a private setting within the study facility by trained and experienced qualitative researchers. All sessions were conducted in Swahili, audio-recorded with participant consent, and supplemented with field notes to capture non-verbal cues and contextual observations.

## Data Management and Analysis

Audio recordings were transcribed verbatim and, where necessary, translated into English. Data were analysed using reflexive thematic analysis as described by Virginia Braun and Victoria Clarke, following established guidance [45,46]. The analytic process involved repeated reading of transcripts to achieve familiarisation, systematic generation of initial codes as per TFA, and iterative development and refinement of themes.

Coding was conducted using both inductive and deductive approaches, guided by the study objectives while remaining responsive to emerging patterns in the data. Data management and coding were supported by NVivo 15, including its AI-assisted features to facilitate data organisation and retrieval.

To enhance rigour, coding and theme development were discussed among members of the research team, and discrepancies were resolved through consensus.

# Trustworthiness and rigour

Several strategies were employed to ensure the credibility and rigour of the findings. These included triangulation of data sources (participants and staff), use of multiple data collection methods (IDIs, KIIs and FGDs), and iterative discussions within the research team.

Thick descriptions of participants' experiences were maintained to support transferability, while an audit trail of analytical decisions was documented to enhance dependability and confirmability.

Ethical approval was obtained from the Ifakara Health Institute Institutional Review Board (IHI/IRB/No: 23-2025). All participants provided written informed consent before enrolment and were assured that their privacy and the confidentiality of the information they provided would be strictly protected. The study was conducted in accordance with the ethical principles of the World Medical Association Declaration of Helsinki[47].

## Results

# Participant characteristics

A total of 24 participants were included in the qualitative study, comprising 7 in-depth interview (IDI) participants, 5 key informants (KIIs), and 12 focus group discussion (FGD) participants. Overall, more than half of participants were aged 20–29 years (54.2%), while 37.5% were aged 30–39 years and 8.3% were aged 40 years or older.

Most participants were female (91.7%), reflecting the study's focus on pregnant women and maternal nutrition experiences. All IDI and FGD participants were women, while the KII group included both female (60.0%) and male (40.0%) health and research staff. Slightly more than half of all participants were married (54.2%), with marriage being more common among FGD participants (66.7%) and IDI participants (57.1%), whereas most KIIs were single (80.0%).

Regarding education, primary education was the most common level among participants overall (41.7%), followed by secondary education (37.5%). All KII participants had college or university-level education, consistent with their professional roles.

In terms of occupation, small-scale vending was the most common livelihood among participants (62.5%), particularly among IDI (71.4%) and FGD participants (83.3%). Microentrepreneurs were about

12.5%, one IDI participant (4.2%) was a homemaker; and all KIIs (20.8%) were health or research staff (Table 1).

Table 1
Socio-demographic characteristics of study participants by data collection method

| Characteristics | IDIs (n = 7) | KIIs (n = 5) | FGDs (n = 12) | Total (N = 24) |
|---|---|---|---|---|
| Age category, years | | | | |
| 20–29 | 5 (71.4) | 2 (40.0) | 6 (50.0) | 13 (54.2) |
| 30–39 | 1 (14.3) | 2 (40.0) | 6 (50.0) | 9 (37.5) |
| ≥ 40 | 1 (14.3) | 1 (20.0) | 0 (0.0) | 2 (8.3) |
| Sex | | | | |
| Female | 7 (100.0) | 3 (60.0) | 12 (100.0) | 22 (91.7) |
| Male | 0 (0.0) | 2 (40.0) | 0 (0.0) | 2 (8.3) |
| Marital status | | | | |
| Married | 4 (57.1) | 1 (20.0) | 8 (66.7) | 13 (54.2) |
| Single | 3 (42.9) | 4 (80.0) | 4 (33.3) | 11 (45.8) |
| Education level | | | | |
| Primary | 4 (57.1) | 0 (0.0) | 6 (50.0) | 10 (41.7) |
| Secondary | 3 (42.9) | 0 (0.0) | 6 (50.0) | 9 (37.5) |
| College/University | 0 (0.0) | 5 (100.0) | 0 (0.0) | 5 (20.8) |
| Occupation | | | | |
| Small vendor | 5 (71.4) | 0 (0.0) | 10 (83.3) | 15 (62.5) |
| Microentrepreneur | 1 (14.3) | 0 (0.0) | 2 (16.7) | 3 (12.5) |
| Homemaker | 1 (14.3) | 0 (0.0) | 0 (0.0) | 1 (4.2) |
| Health/research staff* | 0 (0.0) | 5 (100.0) | 0 (0.0) | 5 (20.8) |

**Includes nutrition officer, research assistant (chef), clinician, nurse, and pharmaceutical technician.*

# Feeling safe and supported (Affective attitude)

Participants generally described positive emotional responses to the intervention, particularly due to the supportive care environment and continuous monitoring. Many reported feeling reassured by the presence of healthcare staff and the structured nature of the facility-based stay. These positive affective experiences were consistently reported across both IDIs and FGDs. As illustrated by participants:

*“I felt safe because the nurses were always nearby if anything happened.” (IDI participant)*

*“Staff were very friendly and supportive; they treated us with respect regardless of age.” (FGD participant)*

Some negative experiences were also reported, particularly relating to physical discomfort and emotional distress. Participants highlighted concerns about poor mattress quality, which caused discomfort among pregnant women, including pain around the ribs. In addition, temporary separation from family members contributed to emotional strain. These issues were noted not only by pregnant women but also by research staff. A key informant explained:

*“The mattresses were not comfortable for pregnant women; some experienced pain, especially around the ribs.” (KII participant)*

# Understanding built trust (Intervention coherence)

Participants’ understanding of the study improved progressively over time, which played a key role in building trust in the intervention. Although antenatal clinics were widely regarded as trusted sources of information, initial misconceptions and community rumours generated uncertainty and hesitation. Ongoing education and repeated clarification helped to address these concerns, reduce fears, and strengthen confidence in the study. These experiences were consistently reported across participant groups, as evidenced by the following quotations.

*“At first, there were many rumours, and people were afraid, but after explanations and seeing the results, trust increased.” (FGD participant)*

*“Participants received detailed explanations, but some still had concerns that required further clarification.” (KII participant)*

*“When we understood the purpose of the study, we became more confident to continue.” (IDI participant)*

# Perceived benefits encouraged adherence (Perceived effectiveness)

Participants identified clear health and nutritional benefits associated with the intervention, which reinforced their willingness to continue participating. Reported benefits included improved appetite, enhanced overall wellbeing, and positive pregnancy outcomes. These perceived gains were consistently described as key motivators for adherence across participant groups. As illustrated by participants:

*“We were getting nutritious food on time, and that helped us feel stronger during pregnancy.” (IDI participant)*

*“Many participants believed the meals and supplements improved their health and the baby’s growth.” (KII participant)*

*“We gave birth to healthy and active babies, which gave us confidence in the study.” (FGD participant)*

# Adapting to dietary routines (Burden)

Participation in the study imposed several practical and physical challenges that shaped participants’ experiences of burden. These included prolonged stays at the facility, separation from family responsibilities, dietary restrictions, and discomfort associated with some study procedures. In particular, adapting to structured meal plans and portion control was reported as demanding, especially among pregnant participants with increased appetites. A consistent pattern across participant groups emerged, as demonstrated in the following quotes.

*“Staying away from home for many days was difficult, especially leaving children behind.” (IDI participant)*

*“Some participants struggled with portion sizes because they were used to eating more during pregnancy.” (KII participant)*

*“The juice sometimes caused nausea and vomiting, which made the experience uncomfortable.” (FGD participant)*

# Balancing family and economic responsibilities (Opportunity costs)

Participation in the study required women to navigate competing household responsibilities and income-generating activities, highlighting the opportunity costs associated with involvement. Decision-making was often collective rather than individual, with spouses and other family members playing a significant role in determining participation. Although financial compensation was viewed as helpful, many participants perceived it as insufficient to offset the economic losses incurred during their stay at the facility. These experiences were consistently described across participant groups, as reflected by in the following participant quotations:

*“I had to talk with my husband before joining because I would be away from home.” (IDI participant)*

*“Women could not decide alone; family and partners influenced the decision.” (KII participant)*

*“The money helped, but it was not enough compared to what we lost while staying at the facility.” (FGD participant)*

# Aligning with values and social norms (Ethicality)

Acceptability of the intervention was strongly influenced by cultural beliefs, social norms, and prevailing community perceptions. Initial misconceptions particularly regarding B12 supplements and blood sampling were contributed to hesitation and reduced trust. Some participants associated study procedures with negative or supernatural connotations, while others expressed fears about potential adverse outcomes, such as abnormal births. However, these concerns diminished over time as participants received clarification from healthcare providers and observed positive outcomes. These experiences were consistently reported across participant groups, as evidenced by the following quotations:

> *"Some people believed the blood samples were linked to bad intentions or supernatural issues." (KII participant)*

> *"There were fears in the community about having abnormal babies, but these reduced after seeing positive outcomes." (FGD participant)*

> *"After getting explanations from health workers, we felt more comfortable participating." (IDI participant)*

# Coping and staying committed (Self-efficacy)

Despite the challenges encountered, participants demonstrated notable adaptability and resilience in engaging with the intervention. Support from healthcare staff, peer encouragement, and ongoing education were key enablers that strengthened participants' confidence in their ability to comply with study requirements and sustain participation. These facilitators of self-efficacy were consistently described across participant groups, as demonstrated in the following citations:

> *"Even though some foods were difficult at first, we got used to them with time." (IDI participant)*

> *"Education sessions helped participants understand and follow the program better." (KII participant)*

> *"We encouraged each other and shared experiences, which made it easier to continue." (FGD participant)*

## Discussion

This study applied the Theoretical Framework of Acceptability (TFA) to examine participants' lived experiences of a facility-based nutritional intervention among pregnant women. Overall, findings indicate that acceptability was dynamic and multidimensional, shaped by emotional responses, understanding of the intervention, perceived benefits, and contextual constraints. Across all domains, acceptability evolved over time, highlighting the importance of continuous engagement and supportive implementation strategies.

# Feeling safe and supported (affective attitude)

Positive emotional responses highlight the central role of perceived safety and respectful care as key mechanisms shaping intervention acceptability. A supportive environment appeared to reduce uncertainty and promote engagement, particularly in a context where pregnancy may increase vulnerability. At the same time, reported discomfort and emotional strain indicate that affective responses are highly sensitive to both physical conditions and social disruption.

This finding extends existing evidence by showing that, within controlled feeding settings, environmental comfort and interpersonal care are not peripheral but central to sustaining participation. Previous studies have similarly shown that patient-centred care and provider attitudes influence satisfaction and continued engagement in maternal and clinical interventions [33,48–51].

These results indicate that interventions should prioritise not only clinical quality but also participant comfort and dignity. Ensuring adequate facility infrastructure, including appropriate bedding, and integrating psychosocial support may improve participant experience and retention. Future research should further examine how environmental and interpersonal factors interact to shape emotional responses in controlled intervention contexts.

# Understanding built trust (intervention coherence)

Improved understanding over time emerged as a key mechanism for building trust, indicating that acceptability develops through sustained engagement rather than remaining static. Initial uncertainty, driven by rumours and misconceptions, highlights the limitations of one-time information provision. As participants gained clarity on study objectives and procedures, confidence increased, reinforcing continued participation.

This finding extends existing evidence by demonstrating that, in controlled intervention settings, trust is actively constructed through iterative communication rather than assumed at enrolment. Previous studies have similarly shown that comprehension is central to trust-building, particularly in contexts where misinformation may circulate [52,53].

These results indicate that continuous, culturally appropriate communication is essential for maintaining intervention coherence. Embedding regular feedback mechanisms and community engagement throughout the study can strengthen understanding and address emerging concerns. Future research should examine adaptive communication strategies that respond dynamically to participants' evolving informational needs.

# Benefits encouraged adherence (perceived effectiveness)

Perceived health and nutritional benefits emerged as a key mechanism driving adherence, indicating that observable and experiential gains reinforce sustained engagement. Participants' interpretations of

improved wellbeing and positive pregnancy outcomes contributed to a strong sense of value in the intervention, supporting continued participation.

This finding extends existing evidence by demonstrating that, in controlled feeding contexts, perceived effectiveness operates as a behavioural driver that may be independent of clinically measured outcomes. Previous studies have similarly shown that perceived benefits may influence sustained participation in health interventions [54,55].

The results have indicated that interventions should ensure that benefits are both tangible and visible to participants. Incorporating feedback mechanisms, such as regular health monitoring or progress updates, may strengthen perceived value and adherence. Future research should examine how perceived and objectively measured effectiveness interact to influence engagement in maternal nutrition interventions.

# Adapting to dietary routines (burden)

The intervention imposed multiple, cumulative burdens, including dietary adjustments, physical discomfort, and prolonged separation from home environments, which collectively shaped participants' experiences of acceptability. These demands highlight that burden is not a single factor but an accumulation of practical and physical challenges that can constrain engagement.

This finding extends existing evidence by showing that, in controlled feeding settings, the intensity and combination of burdens are critical determinants of adherence rather than the presence of burden alone. Previous studies similarly indicated that high intervention burden can reduce participation and negatively affect wellbeing [56,57].

These results suggest that reducing unnecessary rigidity in dietary protocols and improving participant comfort are essential for enhancing feasibility. Incorporating participant feedback during implementation may help identify and address burdens early without compromising study objectives. Future research should examine how acceptable levels of burden can be balanced with scientific rigor in controlled nutrition interventions.

# Balancing family and economic responsibilities (opportunity costs)

Participation required ongoing negotiation of household responsibilities and income-generating activities, reflecting the broader socio-economic context in which participants live. The need for family approval and the perceived insufficiency of compensation highlights the indirect costs associated with participation and the constraints that might have been imposed on this engagement.

This finding extends existing evidence by demonstrating that acceptability is not solely an individual decision but is embedded within household and community dynamics. Previous studies have similarly

shown that economic constraints and social structures play a critical role in shaping participant's decisions making [58,59].

These results indicate that interventions should incorporate context-sensitive support mechanisms to reduce opportunity costs. Strategies such as adequate compensation, flexible participation models, and family-inclusive engagement may improve feasibility and sustained participation. Future research should examine context-specific approaches to minimising opportunity costs while maintaining ethical standards.

# Alignment with values and social norms (Ethicality)

Cultural beliefs and social norms played a central role in shaping early perceptions of the intervention, particularly in relation to biomedical procedures. Misconceptions highlight the importance of aligning research practices with local value systems to support acceptability. Over time, increased familiarity and observation of positive outcomes appeared to reduce these concerns, indicating that ethical acceptability evolves through ongoing trust-building processes.

This finding extends existing evidence by demonstrating that ethical acceptability is dynamic and shaped through continued engagement rather than being established solely through formal approval procedures. Previous studies similarly emphasised the role of culturally sensitive engagement in addressing concerns and improving acceptability in comparable settings [60,61].

These results indicate that ethical practice should incorporate sustained dialogue with participants and communities throughout the study. Involving community leaders and using culturally appropriate communication strategies may enhance alignment with local norms and strengthen trust. Future research should examine how ethical perceptions evolve over time and influence long-term participation.

# Coping and staying committed (self-efficacy)

Participants demonstrated increasing confidence in their ability to engage with the intervention despite initial challenges, indicating that self-efficacy developed progressively through participation. Support from peers, healthcare staff, and ongoing education facilitated this process, enabling participants to adapt to intervention demands and overcome early difficulties.

This finding extends existing evidence by showing that, in controlled feeding contexts, self-efficacy is actively built through social support and experiential learning rather than being a fixed individual attribute. Previous studies similarly highlighted the role of supportive environments in strengthening confidence and sustained engagement in health interventions [62,63].

These results indicate that interventions should intentionally foster supportive structures that promote shared learning and encouragement. Integrating peer support mechanisms and continuous education may enhance sustained participation and adherence. Future research should examine how different forms of support interact to influence self-efficacy and long-term engagement in similar settings.

# Strengths and limitations

This study benefits from the use of multiple qualitative methods, enabling triangulation across participants and stakeholders' perspectives and enhancing the credibility of findings. The application of a theoretical framework provided a structured approach to analysing acceptability across domains. However, social desirability bias may have influenced responses due to close interaction with study staff. Additionally, the context-specific nature of the study may limit transferability to other settings or intervention types.

## Closing synthesis

Overall, acceptability emerged as a dynamic process shaped by ongoing interaction between participants, the intervention, and the broader social context, underscoring the need for flexible, participant-centred approaches in designing and implementing controlled feeding studies.

## Conclusions

Acceptability of controlled feeding and vitamin B12 supplementation among pregnant women is shaped by evolving emotional, cognitive, and contextual experiences. Interventions that provide supportive environments, foster continuous understanding, and account for participants' social and economic realities are more likely to achieve sustained engagement. Integrating participant-centred and culturally responsive approaches is essential for improving feasibility and ethical implementation of maternal nutrition interventions in low-resource settings. Future research should focus on developing scalable strategies that minimise participant burden and opportunity costs while maintaining scientific consistency.

## Abbreviations

FGD
Focus Group Discussion
IDI
In–depth interviews
ICH
GCP–International Conference on Harmonisation–Good Clinical Practice
IHI
Ifakara Health Institute
IRB
Institution Review Board
KII
Key informant interviews

TFA
Theoretical Framework of Acceptance

## Declarations

### Ethics approval and consent to participate

The study was conducted in accordance with the ethical principles outlined in the International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) guidelines. Ethical approval was obtained from the Institutional Review Board of the Ifakara Health Institute (IHI-IRB). Following approval, permission to conduct the study was formally communicated to local government authorities, including Bagamoyo District administrative officials. Eligible participants were invited through phone calls and coordination with local leaders to attend the consenting process at the Ifakara Health Institute, Bagamoyo Clinical Trial Facility, where written informed consent was obtained from all participants prior to enrolment.

### Consent for publication

Not applicable.

## Competing interests

The authors declare that they have no competing interests.

## Funding

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## Author Contribution

O.L conceived the study, secured funding, and served as the principal investigator. M.M, H.T.B, and A.M developed the interview guide and obtained ethical approval. H.T.B conducted the interviews, transcribed, developed the codebook, coded and analysed the qualitative data, interpreted the findings, and drafted the manuscript. M.M transcribed and coded the interview transcripts and critically reviewed the manuscript. B.B and R.S coordinated participant recruitment and community sensitisation. M.M, Z.L, H.M, and H.H.M critically reviewed the manuscript and provided intellectual input. All authors contributed to the interpretation of the findings, read, and approved the final manuscript.

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# Data Availability

The datasets generated and/or analysed during the current study are not publicly available due to their use in ongoing analyses, planned publications and they contain information that could compromise participant confidentiality. De-identified data may be made available from the corresponding author on reasonable request, subject to approval by the relevant ethics committee and institutional data-sharing policies.

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# Figures




**Figure 1**

*Graph 1: The theoretical framework of acceptability (adapted from Paynter et al., 2023; and author's innovation)*[35]

# Supplementary Files

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