

APPENDIX A: WOMEN IDI GUIDE

A phenomenological qualitative study of the acceptability, lived experiences, and ethical perspectives of pregnant women participating in a controlled feeding vitamin B12 supplementation trial in Bagamoyo, Tanzania

Demographics

Ask each participant to introduce herself and share her approximate age, education, etc. as shown in the table below.

Region: District:
 Ward:
 Name of Village/Township:
 Date: ____/____/____ Time, start: ____/____ Finish: ____/____
 (Duration: ____)
 Name of Moderator: Name of Note-taker:
 Category of KII Participant

No	Participant's ID (Use title)	Age	Sex	Marital status	Level of education	Occupation

Line of Inquiry

Questions for IDI

Theme	Key Question	Issues
Understanding willingness and ability to participate	Can you tell me how you decided to participate in this controlled feeding study?	▪ Motivation ▪ Decision-making ▪ Expectations ▪ Family influence ▪ Cultural beliefs ▪ Financial considerations

Section A: Understanding willingness and decision to participate

1. Can you describe how you first heard about this study?

Probe

- a) *Who introduced the study?*
- b) *What interested you?*
- c) *What was your first impression?*

2. What influenced your decision to participate?

Probe

- *Health benefits*
- *Baby's health*
- *Trust in researchers*
- *Financial compensation*
- *Family encouragement*

3. Did anyone influence your decision?

Probe

- *Husband*
- *Parents*
- *Friends*
- *Community members*

- *Health workers*

4. Did you have any concerns before joining?

Probes

- *Food*
- *Blood collection*
- *Staying at the facility*
- *Supplements*
- *Safety*

Section B: Recruitment and informed consent

Theme	Key Question	Issues
Recruitment and intervention coherence	Can you describe your experience of the recruitment and consent process, and how it influenced your decision to participate in the study?	▪ Clarity of study information ▪ Understanding of study purpose and procedures ▪ Opportunity to ask questions ▪ Voluntariness and autonomy ▪ Trust in researchers ▪ Initial concerns or misconceptions ▪ Family involvement in decision-making ▪ Expectations before enrolment

5. How was the study explained to you?

Probes

- Was everything clear?*
- What was difficult to understand?*
- Did you ask questions?*

6. Did you feel free to decide whether or not to participate?

Probes

- Did anyone pressure you?*
- Were you given enough time?*
- Did you feel comfortable saying no?*

Section C: Experiences during the controlled feeding intervention

Theme	Key Question	Issues
Experiences during facility stay and dietary intervention	Can you describe your experiences of staying at the study facility and participating in the controlled feeding intervention?	▪ Facility environment and comfort ▪ Daily routines ▪ Food quality, quantity and variety ▪ Cultural acceptability of meals ▪ Adherence to dietary requirements ▪ Physical discomfort or side effects ▪ Interactions with study staff ▪ Peer relationships ▪ Separation from family ▪ Overall satisfaction

7. Can you describe your experience staying at the study facility?

Probe

- *Daily routine*
- *Comfort*
- *Sleeping arrangements*
- *Missing home*

8. How did you experience eating the meals provided?

Probe

- Taste
- Quantity
- Variety
- Cultural acceptability
- Meal schedule

9. Did you experience any challenges during the dietary intervention?

Probes

- Hunger
- Nausea
- Boredom
- Food restrictions
- Following study rules

10. How did the study staff support you?

Probes

- Respect
- Communication
- Responsiveness
- Emotional support

Section D: Experiences of financial compensation

Theme	Key Question	Issues
Financial compensation and ethical perspectives	How did you experience the financial compensation provided during the study, and how did it influence your participation?	▪ Perceived fairness of compensation ▪ Adequacy of compensation ▪ Opportunity costs ▪ Compensation versus reimbursement ▪ Household financial needs ▪ Influence on enrolment ▪ Influence on continued participation ▪ Freedom to withdraw ▪ Perceived coercion or undue inducement ▪ Recommendations for fair compensation

11. What did you think about the compensation you received?

Probe

- a) Was it fair?
- b) Was it enough?
- c) Why?

12. How did the compensation influence your decision to participate?

Probes

- a) Would you have participated without it?
- b) Was it one reason or the main reason?

13. What did you use the compensation for?

Probes

- Household expenses
- Transport
- Food
- Baby needs
- Savings

14. Do you think the compensation reflected what you gave up to participate?

Probe

- Time
- Work
- Family responsibilities
- Income

15. Did the compensation ever make you feel that you should remain in the study even when participation became difficult?

Probe

- Why?
- Did you ever consider withdrawing?
- What influenced your decision?

16. What would you consider to be fair compensation for women participating in similar studies?

Probes

- Amount
- Time
- Burden
- Lost income
- Family responsibilities

Section E. Perceptions and attitudes

Theme	Key Question	Issues
Experiences, perceptions and attitudes towards the study	Looking back on your participation, how would you describe your overall experience of the study?	▪ Overall satisfaction ▪ Positive experiences ▪ Challenges encountered ▪ Perceived health benefits ▪ Changes in perception over time ▪ Trust in research ▪ Meaning of participation ▪ Personal learning ▪ Family and community reactions ▪ Willingness to participate again

17. Looking back, how would you describe your overall experience?

Probe

- Most positive experience
- Most difficult experience

18. Did your opinion about the study change over time?

Probes

- Why?
- What changed?
- What increased your confidence?

19. What did participating in this study mean to you personally?

Probes

- Personal growth
- Pregnancy
- Research
- Helping others

Section F. Recommendations for future studies

Theme	Key Question	Issues
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Recommendations for improving future controlled feeding studies	Based on your experience, what recommendations would you make to improve future controlled feeding studies involving pregnant women?	▪ Recruitment strategies ▪ Consent process ▪ Communication ▪ Facility environment ▪ Dietary intervention ▪ Participant support ▪ Financial compensation ▪ Community engagement ▪ Trust-building ▪ Ethical considerations ▪ Improving participant experience
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20. What would you change if this study were conducted again?

Probes

- *Food*
- *Facility*
- *Staff*
- *Communication*
- *Compensation*

21. What advice would you give researchers planning similar studies?

Probes

- *Recruitment*
- *Consent*
- *Participant support*
- *Respect*
- *Compensation*

22. Is there anything else about your experience or about the financial compensation that we have not discussed but that you think is important for researchers to know?

Closing remark

Thank you all for your time and valuable insights. Your experiences and feedback are crucial in helping us improve future controlled feeding studies. We truly appreciate your willingness to share your thoughts, as this will contribute to better study designs and participant experiences. Please remember that everything discussed here will remain confidential. Once again, we appreciate your participation and thoughtful contributions.

THE END

APPENDIX B: WOMEN FGD GUIDE

A phenomenological qualitative study of the acceptability, lived experiences, and ethical perspectives of pregnant women participating in a controlled feeding vitamin B12 supplementation trial in Bagamoyo, Tanzania

Demographics

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No	Participant's ID (Use title)	Age	Sex	Marital status	Level of education	Occupation

1. Understanding willingness and ability to participate

Theme	Key Question	Issues
Understanding willingness and ability to participate	What motivated you to participate in this controlled feeding study?	▪ Influencing factors in decision-making ▪ External Influences on Participation ▪ Financial compensation and perceived benefits ▪ Household decision-making

1.1 What motivated you to participate in this controlled feeding study?

Probe

- Did you have any expectations before joining?
- Were there any specific benefits you considered?
- Did financial compensation influence your decision?
- Besides compensation, what other factors encouraged you to participate?
- Which factor was most important?

1.2 What concerns, if any, did you have before joining the study?

Probe

- Did you discuss your participation with family or friends?
- What were their views?
- Were you concerned about being away from home?
- Did you have concerns about the compensation provided?
- Did you think the compensation would adequately cover your time or expenses?

1.3 What factors made it easy or difficult for you to participate?

Probe

- Did your work or family responsibilities affect your decision?

- Did the study location or schedule impact your participation?
- Did family responsibilities affect your participation?
- Did financial or work-related responsibilities make participation difficult?
- Did compensation help reduce these challenges?

1.4 How did you first learn about this study?

Probe

- Did the recruitment method influence your decision to join?

1.5 Were there any cultural or social factors that affected your decision to participate?

Probe

- Did community perceptions play a role in your decision?
- Were there any religious or traditional concerns?
- Did community opinions influence your decision?
- Did anyone discourage you from participating?
- Were there beliefs about blood collection, supplements, or staying at the research facility?

2. Financial compensation and ethical perspectives

Theme	Key Question	Issues
Financial compensation and ethical perspectives	What are your views about the financial compensation provided during this study?	▪ Fairness ▪ Adequacy ▪ Opportunity costs ▪ Economic vulnerability ▪ Voluntariness ▪ Undue inducement ▪ Reimbursement versus payment

2.1 How did you feel about the financial compensation you received?

Probes

- Was it fair?
- Was it enough?
- Why?

2.2 What do you think the compensation was intended to cover?

Probes

- Time?
- Lost income?
- Transport?
- Appreciation?
- Something else?

2.3 Do you think financial compensation influenced people's decision to join the study?

Probes

- a) Did it encourage participation?
- b) Would participants still have joined without compensation?
- c) Why?

2.4 Some people argue that financial compensation may persuade people to participate even when they have concerns. Others believe it simply recognises participants' time and effort.

What are your views?

Probes

- a) Did compensation ever make people feel they had to remain in the study?
- b) Did you feel free to withdraw at any time?

2.5 What do you think would be a fair way to determine compensation for future research studies?

Probes

- Time spent?
- Family responsibilities?
- Travel?
- Lost income?
- Difficulty of participation?

3. Recruitment and Consent Process

Theme	Key Question	Issues
Recruitment and consent process	How did you feel about the consent process?	- Clarity and understanding of study requirements. - Participant autonomy and decision-making

3.1 Can you describe your experience with the recruitment process?

Probe

- Was the information given to you clear and understandable?

3.2 How did you feel about the consent process?

Probe

- Did you fully understand the study requirements before signing the consent?
- Were you given enough time to ask questions?

3.3 Were there any challenges you faced during the consent process?

Probe

- Did you feel pressured to participate?

3.4 What could be improved in the recruitment and consent process for future studies?

Probe

- Would you suggest any changes in how information is presented?

4. Experiences during facility stay and dietary intervention

Theme	Key Question	Issues
Experience during facility stay and dietary intervention	How was your experience staying at the study facility?	- Facility comfort and daily life impact - Dietary intervention and acceptability - Social interaction and support from staff

4.1 How was your experience staying at the study facility?

Probe

- Were the conditions comfortable?
- How did the stay impact your daily life?

4.2 What were your thoughts on the meals provided?

Probe

- Were they culturally acceptable?
- Were you satisfied with the variety and quality?
- Were meals culturally acceptable?
- Was the amount of food sufficient?
- Were you satisfied with meal variety?
- Did eating according to the study schedule affect you?

4.3 Did you experience any difficulties with the dietary intervention?

Probe

- Were the meals easy to consume?
- Did you experience any side effects or discomfort?

4.4 What support did you receive from the study staff during your stay?

Probe

- Was the staff responsive to your needs?
- Did staff treat participants respectfully?
- Did staff respond to concerns promptly?
- Did staff help you feel comfortable and safe?

4.5 How did your social interactions change while in the facility?

Probe

- Did you feel isolated from family and friends?

5. Experiences, perceptions and attitudes

Theme	Key Question	Issues
Experiences, perceptions and attitudes	What was your overall impression of the study?	Expectations vs. Reality (If the study meets participants' expectations)

		▪ Impact on daily life (the way participation affect work, family, or personal life) ▪ Challenges and coping strategies (difficulties did participants face, and means to manage them)
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5.1 What was your overall impression of the study?

Probe

- Did it meet your expectations?
- Did your experience match your expectations?
- What surprised you most?

5.2 Did your perception of clinical research change after participating in this study?

Probe

- What did you learn about research participation?

5.3 How did your participation affect your daily life?

Probe

- Did it interfere with work or family responsibilities?
- Family life
- Employment
- Household responsibilities
- Financial situation

5.4 What were the most positive aspects of your participation?

Probe

- What did you enjoy the most?

5.5 What were the most challenging aspects of the study for you?

Probe

- How did you cope with them?

5.6 How did your views about the study change from the beginning to the end?

Probes

- What contributed to those changes?
- Did trust increase over time?
- Did your confidence increase?

6. Challenges and recommendations for future studies

Theme	Key Question	Issues
Challenges and Recommendations for Future Studies	What challenges did you or other participants face during this study?	▪ Logistical Barriers (difficulties related to transport, accommodation, or scheduling). ▪ Community Acceptance and Trust (researchers improve trust and acceptance of controlled feeding studies in the community). ▪ Challenges and coping strategies (difficulties did participants face, and means to manage them).

6.1 What challenges did you or other participants face during this study?

Probe

- Were there any logistical difficulties?

6.2 What support services would have made your participation easier?

probe

- Would financial support, transport, or communication assistance help?
- Financial compensation
- Childcare
- Flexible schedules
- Communication
- Transport

6.3 What changes would you recommend for future controlled feeding studies?

Probe

- How can recruitment and consent processes be improved?
- Recruitment

- *Consent*
- *Food*
- *Facility stay*
- *Compensation*

6.4 What could be done to make participation in such studies more acceptable in your community?

Probe

- *How can researchers build trust with the community?*

6.5 Would you consider participating in another similar study in the future?

probe

- *Why or why not?*

6.6 What final thoughts or recommendations do you have for researchers conducting controlled feeding studies?

6.7 If you were advising researchers designing a similar study, what would you recommend regarding financial compensation?

Probes

- *What should compensation consider?*
- *What would be fair?*
- *How can researchers avoid undue influence while recognising participants' contributions?*

THE END

Closing Remark

Thank you all for your time and valuable insights. Your experiences and feedback are crucial in helping us improve future controlled feeding studies. We truly appreciate your willingness to share your thoughts, as this will contribute to better study designs and participant experiences. Please remember that everything discussed here will remain confidential. Once again, we appreciate your participation and thoughtful contributions.

APPENDIX C: PROVIDER KII GUIDE

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Line of Inquiry

Section A: Factors influencing willingness and ability to participate

Theme	Key Question	Issues
Willingness and ability to participate	What factors influence participants' willingness, decision-making, and ability to enrol in and complete a controlled feeding study?	▪ Cultural barriers (e.g., dietary restrictions or concerns about being monitored) ▪ Social and economic constraints ▪ Health and physical limitations ▪ Trust and communication ▪ Gender and family dynamics ▪ Financial compensation and perceived fairness ▪ Motivations for participation

1. From your perspective, what are the main reasons participants decide to join or decline participation in a controlled feeding study?

Probe

- a) Reasons for reluctance to eat provided food
- b) Social/economic situation influencing decision
- c) To what extent does financial compensation influence their decision?
- d) Do participants view the compensation as a benefit, reimbursement, or payment?
- e) Do some participants appear motivated primarily by the compensation?

2. Have you observed any cultural, social, economic, or financial factors that influence participants' decision-making about joining the study?

Probe

How does participants' financial situation affect their willingness to participate?

3. What concerns or expectations do participants commonly express before or during enrolment?

Probe

- a) What did they asked about the type of food they will be given?
- b) Did they had concerns about the length of stay at the facility?
- c) What did they hope to gain from participating in this study?

- d) *What are their expectations regarding financial compensation?*
- e) *Do participants ask whether the compensation is adequate?*
- f) *Do they compare compensation with the time spent away from home or income lost?*

Section B: Financial compensation and ethical considerations

Theme	Key Question	Issues
Financial compensation and ethical perspectives	How do participants perceive the financial compensation provided during the controlled feeding study?	▪ Perceived fairness ▪ Compensation versus reimbursement ▪ Undue inducement ▪ Voluntariness ▪ Economic vulnerability ▪ Participant expectations ▪ Ethical concerns

1. How do participants generally perceive the financial compensation provided during the study?

Probes

- a) *Do they consider it fair?*
- b) *Do they think it adequately compensates for their time and inconvenience?*
- c) *What comments do they usually make?*

2. In your opinion, does financial compensation influence participants' decisions to enrol or remain in the study?

Probes

- a) *Does it encourage participation?*
- b) *Could it influence participants to ignore inconveniences or risks?*
- c) *Have participants ever indicated they joined mainly because of the compensation?*

3. Have participants ever expressed concerns that the compensation was either too low or too high?

Probes

- a) *Why?*
- b) *What amount did participants consider fair?*
- c) *Did perceptions differ across participants?*

4. Based on your observations, do you think participants felt free to decline participation or withdraw after enrolment?

Probes

- a) *Did compensation appear to influence this decision?*
- b) *Were there situations where participants remained because of the compensation?*

5. What ethical considerations should researchers take into account when determining financial compensation in future studies?

Section C: Experiences, Perceptions, and Attitudes

Theme	Key Question	Issues
Experiences, perceptions, and attitudes	Based on your interactions, how would you describe participants' overall experience and attitude toward the controlled feeding study?	▪ Participant satisfaction or dissatisfaction. ▪ Perceptions of the study's purpose and value ▪ Attitudinal changes over time ▪ Trust and relationship with staff ▪ Cultural and personal beliefs

1. How would you describe participants' reactions to the recruitment and consent process?

Probe

- a) *Did they seem to understand the study information clearly?*
- b) *Did they agree to participate easily or need convincing?*
- c) *Were there any questions or concerns they raised before consenting?*

2. What challenges, if any, have you encountered while explaining the study purpose and procedures to participants?

Probe

- a) *Did participants easily understand the purpose of the study?*
- b) *Which part of the explanation seemed most confusing to them?*
- c) *What steps did you take to ensure participants fully understood?*

3. In your view, how do participants perceive the facility stay (e.g., environment, duration, rules)?

4. How do participants respond to the dietary interventions, including the type, quality, and quantity of food provided?

Probe

- a) *Did they accept the type of food provided without issues?*
- b) *How did they feel about the quantity of food they received?*
- c) *Were meals acceptable?*
- d) *Did participants compare meals with those eaten at home?*
- e) *Did the quality of meals influence their satisfaction?*

5. Have you noticed any changes in participants' attitudes during the course of the study? If so, what influenced those changes?

Probe

- a) *Did participants seem anxious at first but later change?*
- b) *What factors contributed to those attitude changes?*
- c) *Did you observe more positive or negative changes?*

6. How do you assess participants' understanding of the study procedures and their role in it?

Probe

- a) *Do you ask them questions to confirm their understanding?*
- b) *What methods do you use to clearly explain the study procedures?*
- c) *What questions do participants ask that show confusion?*
- d) *Are there differences in understanding between different groups of participants?*

Section D: Challenges and recommendations

Theme	Key Question	Issues
Challenges and recommendations for future studies	Based on your experience, what challenges did you face during the study, and what would you recommend to improve future controlled feeding trials?	▪ Operational challenge (e.g., kitchen, clinical, admin). ▪ Participant-related issues (Dropouts, non-compliance with dietary rules, late arrivals, or misunderstandings about procedures). ▪ Communication gaps – Misalignment between participant expectations and study demands, or unclear instructions. ▪ Facility or environmental limitations ▪ Dietary intervention difficulties (Food acceptance, allergies, portion dissatisfaction, or monotony of meals). ▪ Suggestions for improvement.

1. What operational or logistical challenges have you faced during the implementation of the study?

Probe

- *Any challenges in food delivery or preparation.*
- *If participant or staff schedules affected study operations.*
- *Coordination among the research team during implementation.*

2. From your experience, what aspects of the controlled feeding process could be improved to better support participant compliance? **Explain, why you think so?**

3. How do you think communication between study staff and participants could be enhanced?

4. What role does trust play in participant engagement, and how can it be strengthened in future trials?

Probe

- *Factors help participants build trust in the research team*

a) *Have you ever observed a lack of trust? How did it show up?*

5. What recommendations would you give for improving participant comfort and satisfaction during facility stays?
6. What recommendations would you make regarding financial compensation in future controlled feeding trials?

Probes

- a) *How should compensation be determined?*
- b) *What factors should researchers consider?*
- c) *Should compensation vary according to participant burden?*

7. Based on your experience, what should future research teams prioritize when designing and implementing a controlled feeding trial in this setting?

Probe

- a) *What key aspects could improve participant engagement?*
- b) *What changes would you suggest in the planning or implementation of the study?*

THE END