# Applying Human-Centered Design in Formative Research: Developing a Cluster Randomized Controlled Trial for a Culturally Tailored Women's Empowerment Program to Boost Immunization Service Uptake

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## *Abstract*

**Background:** Human-centered design (HCD) is vital for crafting impactful solutions, especially in regions with lower Routine Immunization (RI) coverage, like Northern Nigeria. The Routine Immunization Buddy System (RIBS), a human-centered solution, targets economically disadvantaged caregivers in Northern Nigeria.

**Objective:** Through a community-based participatory approach (CBPA), this study explores caregivers' lives, focusing on socio-economic and health-related factors affecting immunization uptake, aiming to propose interventions for enhancing RI uptake.

**Methods:** Employing a three-step HCD process, including the Discovery, Ideation, and Formulation phases, the study conducted Focus Group Discussions (FGDs) and Key Informant Interviews (KIIs) for caregivers and stakeholders capable of influencing the woman decision within a health setting. Semi-structured interviews facilitated an in-depth exploration of participants' experiences. Data collection utilized audio/video recordings, detailed notes, and observation sessions. Data analysis encompassed transcription, descriptive, and thematic analysis to inform evidence-based interventions.

**Results:** The study found significant socio-cultural variations shaping healthcare access and decision-making among caregivers in Kaduna State were unveiled. Economic constraints and logistical challenges hindered healthcare access, particularly in rural areas. Marital dynamics showcased varying levels of spousal support and women's autonomy in healthcare choices. Caregivers expressed strong aspirations for economic empowerment, underscoring a collective yearning for personal and community advancement. Community-led initiatives, like advocacy campaigns and peer support networks, emerged as promising strategies to mitigate healthcare disparities.

**Conclusions:** Tailored interventions, informed by study findings, hold promise in addressing health disparities among Kaduna State caregivers. By addressing economic empowerment, fostering community-led advocacy, and establishing peer support networks, caregivers can make informed health decisions, contributing to community development. The findings from this research is being given strong consideration in the design of our cRCT study that aim to empower women to make informed decision about taking up immunization services.

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# Applying Human-Centered Design in Formative Research: Developing a Cluster Randomized Controlled Trial for a Culturally Tailored Women's Empowerment Program to Boost Immunization Service Uptake

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**Abstract**

**Background:** Human-centered design (HCD) is vital for crafting impactful solutions, especially in regions with lower Routine Immunization (RI) coverage, like Northern Nigeria. The Routine Immunization Buddy System (RIBS), a human-centered solution, targets economically disadvantaged caregivers in Northern Nigeria. Through a community-based participatory approach (CBPA), this study explores caregivers' lives, focusing on socio-economic and health-related factors affecting immunization uptake, aiming to propose interventions for enhancing RI uptake. **Methods:** Employing a three-step HCD process, including the Discovery, Ideation, and Formulation phases, the study conducted Focus Group Discussions (FGDs) and Key Informant Interviews (KIIs) for caregivers and stakeholders capable of influencing the woman decision within a health setting. Semi-structured interviews facilitated an in-depth exploration of participants' experiences. Data collection utilized audio/video recordings, detailed notes, and observation sessions. Data analysis encompassed transcription, descriptive, and thematic analysis to inform evidence-based interventions. **Results:** The study found significant socio-cultural variations shaping healthcare access and decision-making among caregivers in Kaduna State were unveiled. Economic constraints and logistical challenges hindered healthcare access, particularly in rural areas. Marital dynamics showcased varying levels of spousal support and women's autonomy in healthcare choices. Caregivers expressed strong aspirations for economic empowerment, underscoring a collective yearning for personal and community advancement. Community-led initiatives, like advocacy campaigns and peer support networks, emerged as promising strategies to mitigate healthcare disparities. **Conclusion:** Tailored interventions, informed by study findings, hold promise in addressing health disparities among Kaduna State caregivers. By addressing economic empowerment, fostering community-led advocacy, and establishing peer support networks, caregivers can make informed health decisions, contributing to community development. The findings from this research is being given strong consideration in the design of our cRCT study that aim to empower women to make informed decision about taking up immunization services.

**Keywords:** Routine Immunization, Female Caregivers, Human-Centered Design, Focus group discussions, Key informant interviews, Northern Nigeria

## Introduction

Immunization is an essential, cost-effective strategy to reduce childhood morbidity and mortality, which saves an estimated 2 to 3 million lives each year.[1] Over the years, routine immunization coverage in Nigeria has remained low. Penta-3 coverage rate of 50% indicates that routine immunization (RI) coverage has consistently

lagged.[2] Particularly concerning is the disparity observed across regions, with Northern Nigeria shouldering the heaviest burden of unimmunized children.[3-4] In the North Central, North East, and North West zones, Penta-3 coverage rates are alarmingly low, at 54%, 37%, and 29%, respectively.[2] These findings underscore the urgent need for targeted interventions aimed at improving RI uptake in northern Nigeria to mitigate the risks posed by vaccine-preventable diseases (VPD) and safeguard the health of vulnerable populations.

In contrast, the South-East, South-South, and South-Western zones have higher Penta-3 coverage rates of 83%, 70%, and 74%, respectively. Vaccination coverage was found to improve across the geopolitical zones with increasing mother's wealth and education levels.[2] Demand-related reasons for un- or under-immunization of eligible children in Northern Nigeria are shown in the table below. The Q2 2019 results of the Action-Lot Quality Assurance Sampling (PAPA-LQAS) and Performance Assessment for Performance Management further bolstered these conclusions.[2, 5-8]

**Table 1.** Reasons for under-immunization of eligible children[2]

| Zone | Reasons | | | |
|---|---|---|---|---|
| | Lack of knowledge (%) | Lack of time (%) | Mistrust or fear (%) | Immunization site too far (%) |
| **North Central** | 50 | 16 | 14 | 13 |
| **North East** | 39 | 17 | 27 | 13 |
| **North West** | 37 | 17 | 32 | 13 |

Community involvement, which means creating a cooperative partnership between communities and immunization programs, is highlighted in the WHO 2016 Report on Global Routine Immunization Strategies and Practices (GRISP) as one of the nine crucial investments to attain improved immunization results[9]. Human-centered design (HCD) is an effective approach to fostering community involvement and ownership. Five HCD strategies can be seamlessly integrated into community-based participatory research (CBPR) to enhance results: establish transdisciplinary teams, prioritize empathy, engage and collaborate with "extreme users,"

swiftly prototype, and develop tangible products or services.[10] HCD enables the attainment of a deep understanding of the problem a solution aims to address and a comprehensive grasp of its target users, thus serving as the cornerstone of impactful solutions.[11-12] HCD involves cultivating profound empathy for individuals, uncovering their needs and desires, and crafting customized interventions to address their challenges.[13-14] Only through this comprehensive understanding can a product be developed that resonates with users.[15-18]

Despite ongoing attempts to increase immunization rates, Nigeria has an estimated 3.1 million of the world's unvaccinated children.[17] Demand creation for vaccination is a critical component of national immunization programs, which works to guarantee that parents, caregivers, communities, and stakeholders understand the value of immunization, believe vaccines are safe and effective, have faith in the quality and dependability of services, have the necessary knowledge and drive to get immunized, and follow the recommended schedule.[19] Establishing enduring demand for immunization relies on caregivers and communities having confidence in vaccine safety and effectiveness and in the quality and dependability of immunization services. Caregivers must also possess the requisite information, accessibility, and motivation to adhere to the recommended immunization schedule promptly.[20-21] This formative research was conducted to understand the lifestyle of women within the intervention community, identify key factors influencing the demand for health services and essentials, and explore innovative solutions to address community challenges effectively. The study delineated the desired goals across thematic areas, and clarified challenges and user needs, to develop a culturally-appropriate women empowerment randomized control trial study to enhance routine immunization uptake in the region.

The Routine Immunization Buddy System (RIBS) initiative is tailored to empower unemployed mothers in Nigeria by integrating education with vocational skills training, aiming to enhance immunization coverage. Targeting rural areas with historically low routine immunization rates and a significant population of unemployed mothers, the program seeks to address the vulnerability of children to vaccine-preventable diseases. RIBS establishes a direct linkage between community health systems and economic empowerment initiatives through vocational skill development. Under the RIBS framework, participating mothers were organized into small

support groups and paired with another member within the group. The group leaders received training from community health workers on delivering practical information about vaccines using a teaching tool known as the *Hannun Rigakafi* (Immunization Hand). In addition to vaccination education, RIBS participants received guidance on potential employment opportunities, such as farming, along with relevant tools and training. Integrating vaccination education with vocational training boosts mothers' confidence and motivation to ensure their children complete the essential five routine childhood immunizations.[22] The program's initial implementation was piloted in Kaduna state, Nigeria, with an evaluation component focused on assessing improvements in vaccination knowledge and demand among participants.

## Methods

### Study design

This study was a formative study that utilized a human centered design[23], which is a comprehensive approach to understanding cultural dynamics in designing a women's empowerment program aimed at enhancing immunization service utilization through qualitative data gathering.[24] This method prioritizes gathering insights directly from the target population to inform the development of the program, ensuring that cultural nuances, community perspectives, and social determinants are considered in designing the intervention. The HCD approach fosters collaboration, empathy, and iterative refinement, leading to a more effective and culturally appropriate program tailored to the needs and preferences of the community.[25]

Through collaboration with diverse stakeholders, including head of the house, community leaders, and healthcare professionals, the study aims to develop culturally sensitive and contextually relevant interventions. This process will be useful in modifying an existing intervention or designing a better on that will be tailored to address the disparities in healthcare access and utilization, ultimately enhancing immunization coverage and improving healthcare outcomes within the target community.

### HCD approach

This approach involved a three-step HCD process: (1) Discovery, (2) Ideation (3) formulation, and the

remodification the original randomized control trial (RCT) study concept.

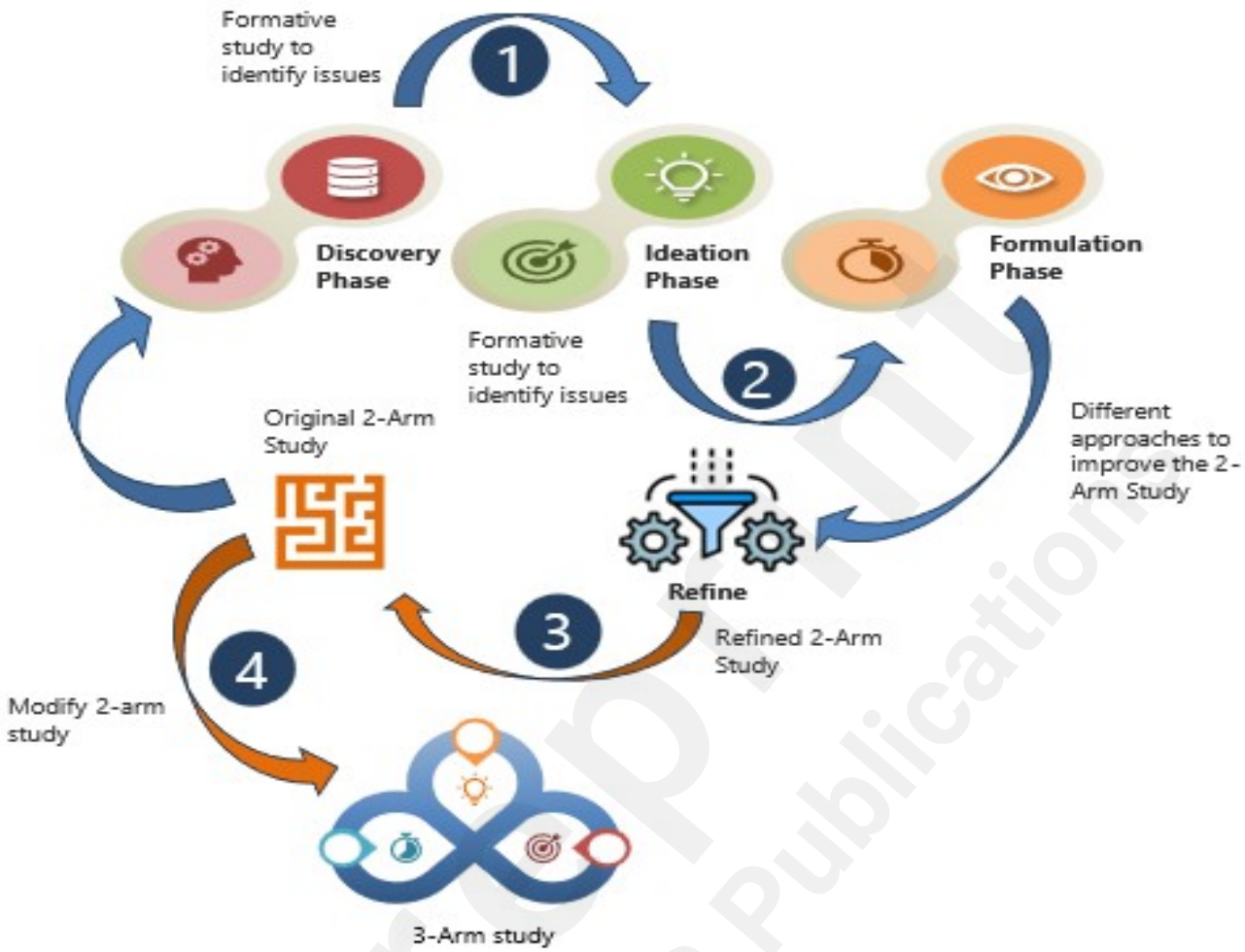


**Figure 1.** The study approach for cRCT study design

**Discovery Phase: Understanding of the lives and experiences of caregivers in community**

This phase employed a community-based participatory approach[26] to provide a comprehensive understanding of the lives and experiences of caregivers in Kaduna State, focusing specifically on the challenges faced by stay-at-home moms. These challenges adversely affect both their children's health and their own, leading to limited access to healthcare services. The study engages with local stakeholders, including community leaders, religious figures, and caregivers, to ensure their active involvement in the research process. This approach acknowledges the importance of community input and collaboration in understanding and addressing immunization challenges effectively.[27-28]

### *Study setting and population*

The study was conducted in a semi-urban and a rural area, specifically targeting communities with distinct religious compositions – one predominantly Christian and the other Muslim. This selection allowed for a holistic contextual understanding of the role of culture and religion in describing the specific socio-economic barriers affecting caregivers in seeking immunization services. Two wards: Kachia ward and Angwan Yelwan Makaranta were selected from Kachia and Soba LGAs local government areas (LGAs), respectively in Kaduna State. While Kachia is a semi-urban settlement with a mix of Christian and Muslim populations, primarily engaged in farming activities such as ginger, yam, maize, and millet cultivation. Angwan Yelwan Makaranta, on the other hand is a rural settlement predominantly inhabited by Muslims, with farming being the main occupation for men.

Focus Group Discussions (FGDs) were strategically tailored to engage caregivers, facilitating dynamic group interactions that encouraged the sharing of collective experiences and perspectives. These discussions provided a valuable space for participants to delve into common challenges and insights related to seeking healthcare, particularly for mothers. Conversely, Key Informant Interviews (KIIs) were designed to tap into the understanding of community stakeholders who play pivotal roles in shaping maternal health-seeking behaviors. These interviews offered deeper insights into the intricate dynamics of community influences on healthcare decisions (Table 2). This approach ensured that the research gathered comprehensive insights, both in terms of breadth and depth. By triangulating findings from these different perspectives, the study delved into specific issues with nuance, thus bolstering the credibility and validity of its research outcomes.

**Table 2.** The sample frame for the qualitative approach

| Study Participants | Number of FGDs | Individuals per FGD | Number for KIIs |
|---|---|---|---|
| Caregivers | 4 | 7 | - |
| **Stakeholders** | | | |
| Husbands | 1 | 7 | - |
| Religious Leaders | 1 | 5 | - |
| Community leaders | 1 | 5 | - |
| Community-women leader | - | - | 1 |
| Market women leader | - | - | 1 |
| **Total** | **7** | **24** | **2** |

### *Tools design*

For the data collection, a sequential approach of FGDs and then KIIs was adopted. The semi-structured FGD guide incorporated an adapted version of the 5C scale, assessing psychological antecedents of vaccination such as confidence, complacency, constraints, calculation, and collective responsibility.[29] This framework guided discussions to uncover barriers and contextual factors influencing immunization uptake, offering a nuanced understanding of caregivers' perceptions and behaviors. This KII guide was developed to follow through with the FGDs for the mothers, exploring issues around women empowerment, financial autonomy, decision making in immunization, and collective agreement in seeking health. Both tools were structured to include an introduction, demographic information, open-ended questions, probing questions, follow-up questions, a closing message, consent and confidentiality assurances. Additionally, the tool enabled gathering information about the social, economic, and health status of community caregivers, including their receptiveness to health interventions involving peer support and economic empowerment.

### *Data collection*

Focus group discussions and key informant interviews were conducted at the Primary Health Center (PHC) Soba in Soba LGA, PHC Kachia, and PHC Gumel in Kachia LGA. This was facilitated by the community health extension workers (CHEWs), community volunteers (CVs) and the community leaders. The data collection included audio and video recordings of the interview processes. Although the questionnaires were prepared in English, interviews were conducted in the preferred dialects of the participants, which was either Hausa and/or English. To safeguard confidentiality and integrity, robust data management protocols were implemented, ensuring secure storage and systematic organization of the collected information. Data collection was conducted over three days.

### *Data analysis*

The plan for data analysis involved the transcription of audio and video recordings from FGDs and KIIs. The transcriptions were coded into relevant themes and analyzed using the grounded theory approach for thematic

analyses.[30-31] This involved two research team members forming concepts from the data and independently identifying several themes. The researchers agreed upon the themes and coded open-ended comments for each theme. We evaluated each comment using the constant comparative method of the grounded theory.[31]

**Ideation Phase: Creative and collaborative process of generating ideas and solutions**

The ideation phase of the study began with brainstorming sessions and collaborative discussions among the research team, caregivers, and community stakeholders. This phase aimed to devise a comprehensive intervention that resonated with the needs and aspirations of caregivers and stakeholders while effectively addressing the research objectives. Various ideas were explored, taking into account factors such as community dynamics, resource availability, and feasibility. Insights were synthesized, and themes were drawn from the results obtained from the discovery phase.

**Formulation Phase: Changing concepts into tangible and achievable interventions**

In the formulation phase of the HCD process, insights and identified opportunity areas were translated into concrete design concepts. This phase focused on brainstorming ideas, refining concepts based on responses from caregivers and stakeholders, and developing solutions that address the needs and challenges identified during the discovery phase. Collaborative co-creation sessions were conducted to engage stakeholders and ensure that the proposed solutions align with the preferences and aspirations of the caregivers.

**Result**

The results presented here reflects the outcome of the different phases of the HCD approach in the formative study to

**Understanding of the lives and experiences of caregivers in community**

The study revealed diverse sociocultural influences, educational challenges, healthcare access barriers, varied family dynamics, and a strong desire for economic empowerment among caregivers in Soba and Kachia communities (Table 3).

**Table 3:** Themes from the ground theory analysis of the interviews

| Themes | Findings |
|---|---|
| Sociocultural Context | Soba and Kachia illustrated how religious diversity influences social norms and cultural behaviors among caregivers |
| Education and Economic Status | Early pregnancy and marriage significantly increase the rate of school dropouts among girls, subsequently limiting their access to further education and economic empowerment opportunities |
| Healthcare Access and Utilization | Caregivers recognized the importance of accessing healthcare for the well-being of themselves and their families. However, they encountered various obstacles that hindered their ability to obtain and utilize healthcare services effectively |
| Family Dynamics and Decision-Making | The study uncovered notable differences in marital dynamics among caregivers, emphasizing variations in spousal support, extramarital affairs, and decision-making autonomy across different communities |
| Future Aspirations and Community Development | Caregivers expressed a strong desire for economic empowerment as a means to enhance their families' standard of living and financial stability |

These findings provide valuable insights into the multifaceted challenges and aspirations within the communities of Soba and Kachia, highlighting the need for targeted interventions that address sociocultural, economic, and healthcare-related issues to promote holistic community development.

**Creative and collaborative process of generating ideas and solutions**

Through discussions, the concept of monthly meetings emerged as a practical approach to foster ongoing engagement and learning among participants. Careful consideration was given to the structure and content of the peer support and education sessions. Tools such as the immunization hand tool and a theme song were proposed to enhance the educational experience and promote retention of information. Drawing from community feedback and contextual understanding, the decision was made to introduce the peer support and education group (Arm 3) alongside the existing financial empowerment group (Arm 2) and control group (Arm 1). The rationale behind incorporating the peer support and education group was rooted in the recognition of the multifaceted nature of empowerment within the community. It was acknowledged that financial empowerment alone might not fully address the diverse needs and perspectives of caregivers. Therefore, the peer support and education group were designed to serve as a platform for knowledge dissemination, social support, and skill-building in addition to the financial intervention. This approach aimed to provide holistic support to caregivers and maximize the intervention's impact on the community's health and well-being.

### Changing concepts into tangible and achievable interventions

The original concept for the cluster randomized controlled trial (cRCT) was a two-arm study that had the control group (Arm 1) and a financial empowerment group (Arm 2). The two-arm study was limited in contextualizing the issues related to financial empowerment at the community level and empowerment to community members meant different things. Based on insights gathered from the ideation phase, the formulation phase of the study was initiated, which was used to address the limitations of the initial two-arm cluster randomized controlled trial (cRCT) by introducing an additional intervention arm. Informed by the insights from the discovery and ideation phases, the study has been modified to include peer support and education group (Arm 3). Participants enrolled in the peer support and education group will go through monthly meetings dedicated to imparting knowledge on immunization and child health. These sessions will utilize tools such as the immunization hand tool, along with the integration of a theme song to enhance engagement and retention of information. The financial empowerment group will receive the same intervention as the peer support group and will also receive financial literacy training and access to microloans. The modification done to optimize the cRCT study is describe in Figure 2.

| | Original study design | Challenge identified | Final study design |
|---|---|---|---|
| 1 | **Two-arm study (control and empowerment)** | ▪ The two arm study was limited in contextualizing the issues related to empowerment at the community level.<br>▪ Community members interpreted empowerment differently | ▪ Three-arm study |
| 2 | **Factorial design that included the following arms:**<br>– **Financial empowerment group**<br>– **Control** | ▪ Financial empowerment alone would not address community-level barriers such as cultural beliefs and perceptions<br>▪ The design did not take into account the role of peer support in encouraging health-seeking behaviour | ▪ Factorial design that included the following arms:<br>– Peer education and support<br>– Financial empowerment group<br>– Control group |
| 3 | **Monitor the utilization of the funds and how it relates to uptake of immunization services** | ▪ There was a disconnect between what the intervention would address and the stakeholder's perception about the key drivers of immunization uptake. | ▪ The new design addresses cooperative financing system to foster collaboration and improve knowledge about immunization services using peer group and support |
| 4 | **Data to be collected at the facility level** | ▪ The data collection source is not exhaustive as to capture all the necessary indicators in the design | ▪ Immunization data from children<br>▪ Socio-demographics data from caregivers<br>▪ Attendance and participation in economic empowerment sessions, immunization, child nutrition, and hygiene knowledge sessions<br>▪ Loans and loan repayment from co-operative groups |

**Figure 2:** Formative research informed intervention design modification

### Discussion

Our aim was to a conduct a formative research that will enable us develop a culturally-appropriate, women-

centric clustered randomized control trial (cRCT) study, aimed to increase awareness of and generate demand for Routine Immunization (RI) services among economically disadvantaged caregivers. We intricately interweaved community engagement throughout the multi-layered, development process to target this program, offering a different perspective for the program. Community involvement through infusing human centered design in formative research have demonstrated effectiveness in promoting behavior change.[32] This formative research report describes the process of using human-centered design within a community-based participatory approach to understand the specific needs and requirements for developing a culturally-appropriate program, to enhance mothers' awareness, support, and economic empowerment, ultimately capable of improving uptake of immunization services.

**Leveraging community groups for health promotion and behavior change**

One effective strategy for lowering vaccine hesitancy is community-led advocacy. Using the voices of the community, this strategy builds community resilience and togetherness while also bolstering vaccine confidence.[33-36] Communities can set the path for higher vaccination rates and better public health outcomes by working together and leveraging local expertise and experiences. The core causes of vaccine hesitancy within certain cultural and social contexts can be effectively addressed by community-led lobbying.[36, 37-39] Advocacy groups can help close the gap between scientific knowledge and community perceptions by customizing messaging to fit local conventions, beliefs, and languages.[35, 40] In addition to fostering inclusivity, this culturally aware approach makes sure that no member of the community is left out.

The community's source of immunization information is crucial in lowering vaccine hesitancy. When advocacy initiatives come from within the community, they are more effective. This grassroots strategy guarantees that the messaging is understood by the community while also fostering trust. A culture of trust and acceptance can be fostered by giving community members the authority to speak out in favor of vaccinations.[41-42] Advocacy campaigns sponsored by the community can cultivate a sense of empowerment and ownership among its members. People who take the initiative to spread factual information about vaccines engage in a proactive role

in preserving the health and welfare of their community. This sense of ownership creates a sense of shared accountability for promoting immunization as a community endeavor and overcoming vaccine skepticism. Traditional and religious leaders also provide valuable counsel and assistance to caregivers. These leaders were frequently regarded as reliable sources of information within the community. These leaders use their power and influence to encourage adherence to advised health practices, debunk myths, and promote positive health behaviors. Traditional and religious leaders are crucial in promoting health education messaging and influencing caregivers' attitudes and behaviors about healthcare by introducing health-related themes into sermons, community meetings, and cultural activities.

The importance of personalized information campaigns such as community mobilization is superior to general messaging in helping overcome vaccine hesitancy, this finding is consistent with other studies.[43-44] Community groups emerge as integral components of the social fabric within the communities, offering caregivers opportunities for socialization, knowledge exchange, and collective support. These groups provide a platform for women to come together, share experiences, and offer mutual assistance in navigating various challenges they faced. Through regular meetings, group discussions, and collaborative activities, caregivers benefit from the wisdom and support of their peers, fostering a sense of solidarity and empowerment within the community. Female associations serve as conduits for disseminating health education messages, promoting healthy behaviors, and mobilizing community action to address common concerns. By leveraging these support groups, caregivers were able to access valuable resources, build social capital, and strengthen their resilience in the face of adversity.

Community groups also offer a forum for the dissemination of health education and information that is appropriate for a certain culture.[45-46] Caregivers can obtain accurate information about illness management, preventive health measures, and available healthcare services through workshops, educational sessions, and group discussions led by reputable community leaders or medical professionals. Health promotion initiatives become more effective when tailored to cultural norms, values, and beliefs of the community. Adapting

messaging to align with these cultural aspects enhances engagement and increases the likelihood of behavior change as cultural adaptations in health interventions aim to make services more linguistically appropriate, culturally competent, and safe, addressing disparities and improving outcomes for diverse populations.[47-50] Community groups present chances for lobbying and group action aimed at removing structural obstacles to healthcare utilization and access. Through the mobilization of caregivers as advocates for enhanced healthcare services, policies, and infrastructure, these groups can bring about significant changes at the community level that will benefit everyone's health.

**Financial empowerment and health decision-making**

There was significant impact of financial empowerment on women's ability to make health-related decisions for themselves and their children. A significant number of women conveyed their desire to have more control over their financial resources, to secure steady source of income and enhance their financial independence, enabling them to prioritize their health and that of their families.

> "*I don't want my children to live the kind of life I'm living now; I want to send them to school so that they can get good jobs"* - A caregiver from Kachia

Financial empowerment plays a crucial role in empowering women to take charge of their health and well-being, ensuring better access to essential healthcare services and medications for both themselves and their families.[51-52] It is a crucial factor influencing women's agency in health decision-making processes. Studies have shown that interventions promoting economic empowerment increase women's involvement in making decisions about their own and their children's well-being.[53-54]

Access to economic power provides women with resources, opportunities, and decision-making authority, enabling them to prioritize health, access healthcare services, and contribute to the overall well-being of their households.[55] This connection between financial empowerment and women's agency in health decisions underscores the importance of addressing economic disparities to enhance women's health outcomes and promote gender equality. By empowering women financially, stakeholders can promote greater autonomy in health decision-making, enhance healthcare utilization rates, and improve health outcomes for women and their

families.

**Sociocultural context, healthcare access and utilization**

Soba and Kachia demonstrate how religious diversity affects social norms and cultural behaviors among caregivers. These communities differ in how women are viewed as empowered and how much autonomy they have in making decisions.

> *"I only interact with other women at social gatherings such as weddings and naming ceremonies" - A caregiver from Soba*

Early pregnancy and marriage greatly raised the percentage of school dropouts among girls, which subsequently limited their access to further education and economic empowerment. For both men and women, agriculture served as the primary source of income, with women actively engaged in small-scale farming and trade.

> *"My academic journey came to an end when I got pregnant in senior secondary school" - A caregiver from Kachia*

Caregivers acknowledged that access to healthcare is critical to preserving and advancing their own and their family's health and well-being. Nonetheless, caregivers face several obstacles that make it difficult to get and make use of healthcare services. Financial constraints are the primary obstacle, preventing many caregivers from obtaining essential prescriptions or accessing timely medical care. Other barriers include concerns about adverse effects following vaccination (AEFI), inadequate availability of supplies and medications at healthcare facilities, resistance from non-consenting spouses, and conflicting religious beliefs, all of which contribute to challenges in accessing immunization services.

> "*It's heartbreaking whenever my children ask for something and I'm unable to provide for them. My baby developed a fever after receiving a vaccine, and my husband was very upset with me*" - A caregiver from Kachia

In rural or underserved locations with inadequate infrastructure and resources, caregivers highlighted difficulties with healthcare facility availability and accessibility. To address systemic problems and enhance vulnerable

groups' access to healthcare, these obstacles highlight the necessity for focused treatments.

"*I trek for thirty minutes to get to the PHC*" - A caregiver from Kachia

While caregivers leveraged on a range of sources for health education and information sharing however, providing accurate and trustworthy information regarding health benefits, preventive measures, and available healthcare services is a critical responsibility of health workers. Health workers support caregivers in better recognizing their own health needs and in seeking appropriate care when needed through one-on-one contacts, counseling sessions, and community outreach programs.

**Implications for the cRCT study design**

The contextual findings in the formative research were instrumental in the thinking of how to modify the original 2-arm study which was identified to have several challenges. Financial empowerment alone would not address community-level barriers such as cultural beliefs and perceptions. The design did not take into account the role of peer support in encouraging health-seeking behavior. The study uncovered a limitation in contextualizing the issues related to empowerment at the community level, as empowerment meant different things to the community members. To ensure we developed a culturally-appropriate study, we modified our initial study design to incorporate a factorial design with three arms: peer support and education, financial empowerment, and a control. This guaranteed that all the most relevant issues that were identified at the formulation phase was incorporated into the final study design.

**Conclusion**

In conclusion, our formative research aimed to develop a culturally-appropriate, women-centric clustered randomized control trial (cRCT) study focused on enhancing Routine Immunization (RI) service uptake among economically disadvantaged caregivers. Through community engagement using human-centered design, we gained valuable insights into barriers to immunization service utilization among mothers. Leveraging community groups for health promotion and advocacy emerged as a powerful strategy to combat vaccine hesitancy and improve public health outcomes. Community-led initiatives was indicated to foster trust, inclusivity, and

empowerment, bridging gaps between scientific knowledge and community perceptions. Financial empowerment emerged as a pivotal factor in women's ability to make health-related decisions and access healthcare services.

Enhancing economic opportunities for women not only promotes agency in health decision-making but also contributes to overall household well-being. Our findings underscore the importance of addressing gender-centered economic disparities to improve women's health outcomes and promote gender equality. The sociocultural context significantly influences healthcare access and utilization, highlighting the need for targeted interventions. Religious diversity, early pregnancy, marriage, and financial constraints were identified as key determinants affecting health-seeking behaviors. Addressing these barriers requires tailored approaches that consider community norms, beliefs, and infrastructure challenges.

These findings have informed modifications to our study design, incorporating peer support, education, financial empowerment, and control arms in a factorial design. This ensures a holistic approach to address community-level barriers and enhance the cultural appropriateness of our intervention. Our formative research lays a solid foundation for a comprehensive cRCT study aimed at promoting immunization uptake and addressing health disparities among vulnerable populations.

**Limitation**

This formative work has certain limitations. One limitation of the study was the potential for response bias during data collection, as respondents may have been hesitant to provide candid responses due to unfamiliarity with the research team. Despite efforts to mitigate this bias through the involvement of local female community resource persons, some degree of reluctance or social desirability bias may have influenced the data. Additionally, the study's focus on specific LGAs within Kaduna State may limit the generalizability of findings to other regions or populations with different socio-cultural contexts. Furthermore, the study's reliance on self-report data, particularly regarding income and daily activities, may have introduced inaccuracies or inconsistencies. Future research could employ more diverse sampling methods and incorporate objective

measures to enhance the robustness and applicability of findings.

## Ethical considerations

The study was conducted in strict compliance with ethical standards for research involving human participants including data collection as required by the Declaration of Helsinki and received ethical clearance with reference number *MOH/ADM/744/VOL.1/601* from the Ethics Research Committee of the Department of Planning Research and Statistics, Kaduna State Ministry of Health after they reviewed and approved the study protocol and informed consent forms made available in English, Hausa and Arabic Languages. All enrolled mothers provided written informed consent.

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## Conflicts of Interest

The authors declare no competing interests related to this research protocol.

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**Abbreviations**

HCD - Human-Centered Design

RI - Routine Immunization

RIBS - The Routine Immunization Buddy System

FGD - Focus Group Discussion

KII - Key Informant Interview

CBPA - community-based participatory approach

SCIDaR - Solina Center for International Development and Research

VPD - Vaccine-Preventable Diseases

LQAS - Action-Lot Quality Assurance Sampling

GRISP - Global Routine Immunization Strategies and Practices

LGA - Local Government Areas

PHC - Primary Health Center

CHEW - Community Health Extension Worker

CV - Community Volunteers (CV)

cRCT - Cluster Randomized Controlled Trial

# Supplementary Files

# TOC/Feature image for homepages

HCD process for cRCT development.