

Protocol

Development and evaluation of a culturally adapted birth preparedness and complication readiness training among Hehe pregnant women in rural Tanzania: exploratory sequential mixed-methods study

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ABSTRACT

Background: Birth preparedness and complication readiness (BPCR) education promotes childbirth preparation, recognition of danger signs, and timely care-seeking. However, translation alone may not ensure that BPCR messages are culturally and conceptually meaningful. The objective of the study is to develop and evaluate culturally adapted BPCR training guided by Cultural Equivalence Theory among Hehe pregnant women in rural Iringa, Tanzania, and assess its effects on knowledge, attitudes, and practices compared with standard Kiswahili-translated training.

Methods: An exploratory sequential mixed-methods design will be used. The qualitative phase will explore women's understanding of BPCR concepts and identify culturally meaningful terminology and explanations. Findings will inform manual adaptation through translation, expert review, community input, cognitive review, and pilot testing. The quantitative phase will use a controlled pretest–posttest quasi-experimental design in two rural districts. BPCR knowledge, attitudes, and practices will be assessed at baseline and approximately four weeks after training. Qualitative data will undergo thematic analysis, while quantitative data will be analyzed using mixed-effects regression and Difference-in-Differences analysis.

Conclusions: The study will assess whether culturally adapted BPCR training provides additional benefits over standard translated training and inform culturally responsive maternal health education in rural Tanzania.

Trial Registration: Pan African Clinical Trials Registry: PACTR202607626025411.

Keywords: Birth preparedness, Complication readiness, Cultural adaptation, Cultural equivalence, Pregnancy, Antenatal care, Maternal health, Mixed methods, Quasi-experimental study, Tanzania

INTRODUCTION

Maternal health services, including antenatal care (ANC), provide an important platform for promoting healthy pregnancy, childbirth, and newborn outcomes. ANC incorporates preventive, screening, clinical, counselling, and educational services that support women throughout

pregnancy and prepare them for childbirth (1). Effective ANC education can improve understanding of complications, appropriate health-seeking behavior, and birth preparedness.^{1,2}

Birth preparedness and complication readiness (BPCR) is an important component of maternal health education.

It encourages pregnant women and their families to anticipate childbirth, recognize potential complications, identify appropriate sources of care, and prepare for timely access to skilled health services.³ Key components include recognizing maternal and newborn danger signs, identifying a place of delivery and skilled birth attendant, preparing financial resources and transport, identifying potential sources of emergency assistance, and planning for timely access to care.^{1,3}

Despite the integration of BPCR education into maternal health programs, studies in low- and middle-income countries have reported gaps in women's knowledge, preparedness, and adoption of recommended practices.⁴ Similar gaps have been documented in sub-Saharan Africa, including limited recognition of danger signs, inadequate financial and transport preparation, and insufficient planning for skilled birth attendance.⁵ These gaps may contribute to delays in recognizing complications and seeking appropriate care.

In Tanzania, ANC services provide opportunities for BPCR education; however, studies continue to report variations in women's BPCR knowledge and preparedness (6). These findings suggest that providing health information is insufficient if messages are not communicated in ways that women understand and can apply within their sociocultural contexts.

Maternal health information is often developed in international or national languages and subsequently translated for use in local settings.⁷ Although Kiswahili is widely used in Tanzanian health services, indigenous languages remain important in many communities. Differences between languages may affect the interpretation of biomedical terminology, concepts, and communication practices.⁸

The Hehe and Kiswahili languages are commonly used in everyday communication within the predominantly Hehe communities of the Iringa Region. Consequently, BPCR education delivered in Kiswahili needs to communicate biomedical concepts in ways that are understandable and culturally meaningful to Hehe pregnant women. Although maternal health interventions have emphasized health education, ANC counselling, and community engagement, limited evidence exists on the additional value of culturally adapting BPCR training beyond standard translation among Hehe pregnant women. In particular, it is important to establish whether incorporating community-informed terminology, explanations, and examples improves BPCR knowledge, attitudes, and practices.

This study will address this gap by developing and evaluating a culturally adapted BPCR training manual guided by Cultural Equivalence Theory and informed by community perspectives. The adaptation will preserve evidence-based clinical recommendations while modifying terminology, expressions, explanations, and examples to improve linguistic and cultural relevance.

The study will compare the adapted training with standard Kiswahili-translated BPCR training to assess the additional contribution of cultural adaptation to BPCR knowledge, attitudes, and practices.

Objectives

Broad objective

To evaluate the effect of a culturally adapted birth preparedness and complication readiness training on knowledge, attitudes, and practices among Hehe pregnant women in the Iringa Region, Tanzania.

Specific objectives

To explore culturally relevant terminology, expressions, meanings, and explanations related to BPCR among Hehe pregnant women. To develop a culturally adapted BPCR training manual guided by Nida's Cultural Equivalence Theory. To determine the effect of the culturally adapted BPCR training manual on BPCR knowledge among Hehe pregnant women in the Iringa Region. To determine the effect of the culturally adapted BPCR training manual on BPCR attitudes among Hehe pregnant women in the Iringa Region. To determine the effect of the culturally adapted BPCR training manual on BPCR practices among Hehe pregnant women in the Iringa Region.

Null hypotheses

Ho1: There is no difference in the knowledge mean score about BPCR between cultural equivalent modified training manual participants and those who are in the standard translated training manual.

Ho2: There is no difference in the attitudes' mean score about BPCR between cultural equivalent modified training manual participants and those who are in the standard translated training manual.

Ho3: There is no difference in the practice mean score about BPCR between cultural equivalent modified training manual participants and those who are in the standard translated training manual.

Study rationale

Linguistic translation alone may not ensure cultural, conceptual, semantic, and experiential equivalence. BPCR messages may remain difficult to understand when translated terms and concepts do not reflect locally meaningful understandings of pregnancy, childbirth, and complications. This study will compare culturally adapted BPCR training with standard Kiswahili-translated training to determine whether incorporating community-informed terminology, explanations, examples, and culturally relevant communication strategies provides additional benefits beyond translation alone.

Theoretical framework

The intervention will be guided by Nida's Cultural Equivalence Theory, which will inform the adaptation of BPCR terminology, concepts, explanations, and examples to preserve intended meanings within the Hehe cultural and linguistic context.⁹ The Health Belief Model will complement this theory by explaining how culturally meaningful information may influence perceived susceptibility, severity, benefits, barriers, cues to action, and self-efficacy related to BPCR. Thus, Cultural Equivalence Theory will guide intervention adaptation, while the HBM will support interpretation of knowledge, attitudes, and practices.¹⁰

METHODS

Study design

The study will use an exploratory sequential mixed-methods design, comprising a qualitative descriptive phase followed by a controlled pretest–posttest quasi-experimental evaluation. The qualitative phase will explore pregnant women's understanding of BPCR content and identify culturally meaningful terminology and explanations. Findings will inform development of the culturally adapted BPCR training manual, which will be evaluated against standard Kiswahili-translated training to assess its effects on BPCR knowledge, attitudes, and practices.

Study setting

The study will be conducted at selected ANC clinics in Kilolo and Mufindi Districts, Iringa Region, Tanzania. Located in the southern highlands, Iringa Region had a population of 1,192,728 in the 2022 Population and Housing Census, comprising 574,313 males and 618,415 females, with approximately 70% residing in rural areas.

Kilolo and Mufindi were selected because they are predominantly rural and include communities where Hehe and Kiswahili are commonly used. These settings are suitable for examining the cultural and linguistic relevance of BPCR education among Hehe pregnant women. ANC services include pregnancy assessment, health education, screening for complications, birth preparedness counseling, and referral. Despite these services, pregnancy-related complications remain a concern, highlighting the importance of knowledge of danger signs, birth preparedness, and timely care-seeking.

The districts will constitute separate study arms: one will receive culturally adapted BPCR training, and the other standard Kiswahili-translated training. District-level allocation will help minimize contamination between groups, although potential differences between districts will be considered when interpreting the findings.

Phase one: qualitative study

Study design

The qualitative phase will use a qualitative descriptive design to explore pregnant women's understanding, perceptions, and interpretation of Kiswahili-translated BPCR educational content. The purpose will be to obtain a clear and practice-oriented description of cultural and linguistic issues relevant to adaptation of BPCR educational materials rather than to develop a phenomenological account of lived experience.

Participants

Participants will be Hehe pregnant women attending ANC in the selected study districts. Eligible participants will be pregnant women in all three trimesters who have lived in the Iringa Region for at least six months, are able to communicate in Kiswahili and are willing to participate in the focus group discussions.

Women will be excluded if they are health workers, are participating in another relevant intervention, have pregnancy complications or medical conditions that prevent participation, or decline participation.

Sampling and sample size

Purposive sampling will recruit pregnant women relevant to the study objectives and Hehe cultural context. Approximately seven focus group discussions, each with eight participants, will be conducted until information saturation is achieved. The final qualitative sample will depend on saturation, not statistical power. Relevant linguistic, maternal health, and methodological experts will also be purposively selected to support translation, cultural adaptation, and review of the intervention materials.

Data collection

Data will be collected using a semi-structured focus group discussion guide to explore participants' understanding of BPCR concepts, interpretation of translated terms, cultural appropriateness, and suggestions for improvement. Trained research assistants fluent in Kiswahili and Hehe will facilitate discussions in private locations. With participants' consent, discussions will be audio-recorded and supplemented with field notes. Each discussion will last approximately 90–120 minutes. Recordings will be transcribed, translated where necessary, and checked for accuracy before analysis.

Cultural adaptation and intervention development

Translation and cultural adaptation framework

BPCR educational content will be translated from English into Kiswahili and culturally adapted for the Hehe context,

guided by Cultural Equivalence Theory and established cross-cultural adaptation principles. The process will preserve the scientific and clinical meaning of BPCR recommendations while improving linguistic, semantic, conceptual, and sociocultural relevance through community-informed terminology and explanations.

Translation and adaptation process

The English BPCR educational content will be translated into Kiswahili by bilingual translators. The translations will be compared and synthesized into one Kiswahili version, which will then be back-translated into English by an independent bilingual translator to assess preservation of meaning.

Experts in linguistics, maternal health, and research methodology will review the translated material. During the qualitative phase, Hehe pregnant women will discuss their understanding of BPCR terms and concepts and suggest locally meaningful alternatives where translations are unclear, unfamiliar, or culturally inappropriate. Community findings will inform revisions to the manual while preserving evidence-based clinical recommendations. The revised material will undergo expert review, back-translation, cognitive review, and pilot testing before finalization. The resulting manual will be called the Culturally Equivalent Modified Training Manual (CEMTM). Adaptations will include modifying difficult terminology, clarifying concepts, and incorporating contextual explanations or visual aids where direct local equivalents for biomedical concepts are unavailable. The adaptation will focus on improving the linguistic, conceptual, and cultural relevance of BPCR education without changing the intended clinical recommendations.

Phase two: quantitative evaluation

Study design

The quantitative phase will use a controlled pretest–posttest quasi-experimental design. Pregnant women in the intervention district will receive the CEMTM, while those in the control district will receive the STTM. Both groups will receive training covering the same core BPCR topics, using comparable delivery procedures, facilitator preparation, and assessment schedules. The main difference will be the cultural adaptation of the educational content in the CEMTM. This design will allow evaluation of the intervention under real-world conditions without individual randomization.

Participants

Eligible participants will be Hehe pregnant women in the first or second trimester who have lived in Iringa Region for at least six months, are willing to participate, and are physically and psychologically able to participate in the study.

Women will be excluded if they are health workers, are participating in another relevant intervention, have pregnancy complications or relevant medical conditions that could substantially affect participation, or decline participation.

Sample size

The quantitative sample size will be calculated using WinPEPI software, version 11.65, based on a comparison of mean BPCR knowledge scores between two independent groups, with a two-sided significance level of 0.05 and 80% statistical power.

Based on findings from a quasi-experimental study conducted in Indonesia, the expected mean knowledge scores will be 60.9 (SD=5.2) for the intervention group and 55.1 (SD=3.4) for the control group, giving an anticipated mean difference of 5.8 points. These parameters will be entered into WinPEPI using the two-independent-means procedure. An additional 10% will be included to account for potential nonresponse or loss to follow-up, resulting in a planned sample of 176 pregnant women, with 88 participants per group.

Sampling and allocation

A multistage sampling procedure will be used to select study areas, followed by systematic sampling to recruit participants. Two of the three rural districts in Iringa Region will be randomly selected based on predefined eligibility criteria. The researcher will designate one selected district as the intervention arm and the other as the control arm. From each district, two divisions, four wards, and eight villages will be selected, giving a total of four divisions, eight wards, and 16 villages. Eligible pregnant women will be identified through ANC attendance or registration records at designated health facilities serving the selected villages and recruited using systematic sampling procedures. District-level allocation will be determined by the researcher, without individual randomization. Since only one district will represent each study arm, differences in district characteristics may influence the findings. Therefore, between-group differences will be interpreted cautiously and not attributed exclusively to the culturally adapted intervention.

Intervention

Culturally equivalent modified training manual

The intervention will consist of structured BPCR education delivered using the CEMTM. The training will cover birth preparedness; recognition of maternal, childbirth, postpartum, and newborn danger signs; preparation for skilled birth attendance; emergency preparedness, including transport and financial arrangements; and appropriate ANC attendance.

The CEMTM will retain core evidence-based BPCR recommendations while incorporating community-informed terminology, locally meaningful explanations, contextual examples, and visual aids where necessary. The adaptation will aim to improve comprehensibility and cultural relevance without altering the intended clinical meaning. Biomedical concepts that lack direct linguistic or cultural equivalents, such as rupture of membranes, vaginal bleeding, and skilled birth attendance, will be explained using appropriate descriptions or visual aids rather than inaccurate literal translations.

Training will be delivered face-to-face by trained maternal health providers using structured teaching, group discussion, explanations, demonstrations where appropriate, and question-and-answer sessions. A total of 16 training sessions will be conducted, comprising eight sessions per study arm. Each session will last two hours and include approximately 11 pregnant women, resulting in 16 hours of training per arm and 32 hours across both arms. Sessions will be conducted at the ANC units of designated health facilities. Trained maternal health providers will use the CEMTM for the intervention arm and the STTM for the control arm.

Both arms will follow standardized timetables and lesson plans to promote consistency in training duration, core content, and delivery. A training assessment checklist will document participants' engagement, including participation in discussions, responses to questions, involvement in demonstrations, and interaction with the facilitator.

Control

Standard Kiswahili-translated training

Participants in the control district will receive BPCR education using the STTM. The training will cover the same core BPCR topics and follow procedures comparable to those in the intervention arm, including training duration and assessment schedules. However, the STTM will not incorporate the community-informed cultural adaptations included in the CEMTM. The control condition will represent standard translated BPCR education rather than a no-intervention condition. This comparison will allow the study to assess the potential additional contribution of cultural adaptation while ensuring that participants in both study arms receive BPCR education.

Intervention fidelity

Intervention fidelity will be promoted through standardized facilitator training, use of the assigned training manual, consistent delivery procedures, supervision by the principal investigator, attendance records, and session monitoring.

Facilitators for the intervention and control arms will be trained separately where feasible to minimize

contamination. The principal investigator will supervise training sessions to assess adherence to the assigned manual and planned procedures and document any deviations. Fidelity monitoring will assess delivery of the intended content, adherence to the planned duration and procedures, appropriate use of the assigned manual, and comparable opportunities for participant interaction and clarification across both study arms.

Outcome measures

Primary outcome: BPCR knowledge

BPCR knowledge will be the primary outcome of the quantitative evaluation. It will be assessed using an adapted 64-item BPCR knowledge instrument. Each item will be scored according to a prespecified answer key, and the total score will represent the number of correctly answered items. Higher scores will indicate greater BPCR knowledge. The instrument will assess knowledge of maternal and newborn danger signs, birth preparedness, skilled birth attendance, financial and transport preparation, and appropriate care-seeking.

Secondary outcome: BPCR attitudes

BPCR attitudes will be assessed using a 15-item Likert-type scale. Items will be scored according to prespecified response categories, with higher total scores indicating more favorable attitudes toward BPCR. The scale will assess participants' perceptions of childbirth preparation, recognition of complications, use of skilled health services, and emergency preparedness.

Secondary outcome: BPCR practices

BPCR practices will be assessed using 12 dichotomous items covering key preparedness behaviors. The total score will be calculated using a prespecified scoring system, with higher scores indicating greater engagement in BPCR practices. Items will address birth planning, financial preparation, transport arrangements, identification of assistance, and other relevant preparedness behaviors.

Covariates

Sociodemographic and obstetric characteristics will be collected as potential covariates. These will include maternal age, educational level, occupation, marital status, gravidity or parity, gestational age, and other prespecified characteristics relevant to BPCR knowledge, attitudes, and practices.

Data collection procedures

Baseline data will be collected before the intervention using a researcher-administered structured questionnaire lasting approximately 15–20 minutes. The same outcome measures will be administered approximately four weeks after the intervention. Research assistants will be trained in

questionnaire administration, informed consent, confidentiality, participant interaction, and data quality. The principal investigator will supervise data collection and check completed questionnaires for completeness and consistency. Procedures will be standardized across study sites to promote consistent data collection and outcome assessment.

Validity and reliability

The BPCR questionnaire will be adapted from established JHPIEGO tools and reviewed for content validity, clarity, and cultural appropriateness by relevant experts. It will comprise 64 knowledge, 15 attitude, and 12 practice items. Reliability will be assessed using KR-20 for knowledge and practice items and Cronbach's alpha for attitude items. Pilot testing will identify and address any issues before the main data collection.

Qualitative data analysis

Qualitative data will be analyzed thematically through coding, theme development, review, and interpretation. The analysis will identify cultural, linguistic, semantic, and conceptual issues affecting understanding of BPCR messages. Findings will inform the cultural adaptation of the BPCR training manual.

Quantitative data analysis

Quantitative data will be analyzed using SPSS version 27. Descriptive statistics will summarize participant characteristics and BPCR outcomes, while baseline characteristics will be examined for group comparability. Mixed-effects linear regression will analyze changes in BPCR knowledge from baseline to the four-week post-test, including study group, time, and the group-by-time interaction, with appropriate covariates. The interaction will assess whether changes differ between groups. Difference-in-Differences analysis will provide a complementary estimate of differential change, with the same framework applied to attitudes and practices as secondary outcomes, where appropriate. Effect estimates will be reported with 95% confidence intervals, using a two-sided significance level of 0.05.

The analysis will account for repeated measurements and clustering at appropriate levels. Because only one district will represent each study arm, findings will be interpreted cautiously, acknowledging potential district-level confounding. The parallel-trends assumption for Difference-in-Differences will be considered, although assessing pre-intervention trends may be limited by having only two districts.

Mixed-methods integration

Integration will connect qualitative findings on cultural and linguistic gaps with the development of the CEMTM and quantitative evaluation of changes in BPCR

knowledge, attitudes, and practices compared with standard translated training. Joint interpretation will explain how community-derived cultural and linguistic considerations relate to the observed outcomes.

Ethical considerations

Ethical approval was obtained from the University of Dodoma Institutional Research Review Board (MA.84/261/86/11). Administrative permissions will be obtained from relevant authorities. All participants will provide informed consent after receiving information about the study, confidentiality, voluntary participation, and the right to withdraw. Approved consent and assent procedures will be followed for participants younger than 18 years.

Risks and benefits

The study is expected to pose minimal risk, although discussing pregnancy complications may cause discomfort. Participants may decline to answer any question or withdraw at any time without penalty. Direct clinical benefits are not guaranteed; however, BPCR training may improve participants' knowledge of birth preparedness and maternal and newborn danger signs. The findings may inform culturally responsive maternal health education.

Withdrawal

Participation will be voluntary, and participants may withdraw at any time without penalty or loss of routine maternal health services. Withdrawal and handling of previously collected data will follow the approved informed-consent procedures and ethical requirements.

Monitoring and quality assurance

The principal investigator will oversee both study phases. Quality assurance will include research team training, standardized procedures, supervision of data collection and intervention delivery, attendance tracking, questionnaire checks, and documentation of protocol deviations. Recruitment, retention, follow-up, intervention fidelity, and potential contamination will be monitored, with corrective actions taken when necessary.

Study timeline

The study will follow an exploratory sequential mixed-methods design, beginning with qualitative exploration to inform cultural adaptation of the BPCR training manual, followed by quantitative quasi-experimental evaluation. Baseline assessments will precede training, with post-intervention assessments conducted four weeks later. The study period is June 2025 to December 2026.

Strengths: The exploratory sequential mixed-methods design will link community perspectives with systematic

cultural adaptation and quantitative evaluation. Comparing culturally adapted BPCR training with standard translated training will help assess the added contribution of cultural adaptation.

Limitations: The quasi-experimental design and allocation of one district to each study arm may limit causal inference due to potential district-level confounding. Self-reported practices may be affected by recall and social-desirability bias. The four-week follow-up may not capture sustained changes, and findings may have limited transferability beyond Hehe pregnant women in rural Iringa.

DISCUSSION

This study will examine whether culturally adapted BPCR training provides additional value beyond standard Kiswahili translation among Hehe pregnant women in rural Tanzania. It addresses the possibility that translation alone may not ensure cultural, linguistic, semantic, and conceptual equivalence in health communication.¹¹

The exploratory sequential mixed-methods design will link qualitative exploration, development of the CEMTM, and quantitative evaluation.¹² Community findings will inform the modification of BPCR terminology and concepts before intervention implementation.

Using standard translated BPCR training as the comparison condition will allow assessment of the additional contribution of cultural adaptation, as both groups will receive education. Knowledge will be the primary outcome, while attitudes and practices will be secondary outcomes. These outcomes may respond differently because changes in attitudes and practices may also depend on household support, financial resources, transportation, health-service availability, and perceived barriers.¹³

The Health Belief Model will help interpret how perceived susceptibility, severity, benefits, barriers, cues to action, and self-efficacy may influence responses to BPCR information (10). However, education alone may not determine preparedness practices, which are also shaped by household and health-system factors.

Interpretation will consider these contextual influences and the limitations of nonrandomized district-level assignment, including potential district-level confounding. The study will also consider whether improved comprehension translates into changes in knowledge, attitudes, and practices, recognizing that these outcomes may change at different rates.

Expected contribution

The study is expected to contribute methodological, empirical, and contextual knowledge. Methodologically, it will demonstrate how community perspectives can inform cultural adaptation of evidence-based BPCR materials.

Empirically, it will assess whether culturally adapted training produces greater improvements in knowledge, attitudes, and practices than standard translated training. Contextually, it will provide evidence on BPCR communication among Hehe pregnant women in rural Iringa Region and may inform adaptation of maternal and reproductive health education for culturally and linguistically diverse populations.

Dissemination

Study findings will be disseminated through publication in peer-reviewed scientific journals, presentations at scientific conferences and academic forums, and communication with relevant maternal health stakeholders. The final study report will be submitted to the University of Dodoma, the Ministry of Health, the President's Office–Regional Administration and Local Government, and the Iringa Regional Secretariat. Findings will also be shared with the Kilolo and Mufindi District Councils.

No individually identifiable participant information will be disclosed during dissemination. The culturally adapted BPCR training materials developed through the study may also be shared with relevant health and academic stakeholders, subject to applicable ethical, institutional, and intellectual property requirements.

CONCLUSION

This study will develop and evaluate culturally adapted BPCR training among Hehe pregnant women in rural Tanzania. Using qualitative exploration and quantitative evaluation, it will compare culturally adapted training with standard Kiswahili-translated training. Findings may inform culturally responsive maternal health education and guide adaptation of interventions for culturally and linguistically diverse populations.

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