

Title: Determine the Preliminary Effectiveness of Mobile CenteringPregnancy to Improve
Maternal and Infant Health Outcomes of Marshallese in Arkansas
PI: Britni Ayers, PhD
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Title: Exploring the Feasibility of Centering Pregnancy with Care Navigation
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Background and Rationale

Pacific Islanders residing in the United States (US) have disproportionately higher rates of preterm birth (<37 completed weeks) and low birthweight infants (<2,500 grams). They are also more likely to experience preeclampsia, primary cesarean birth, excessive gestational weight gain, gestational diabetes mellitus (GDM) and low exclusive breastfeeding initiation and duration at six months compared to other racial/ethnic minorities and the US population in general.¹⁻⁸ Preterm birth is a pressing challenge to maternal, infant, and child health in the US because preterm infants can face lifelong disabilities and are at higher risk of death during their first few days of life.⁹ Early and consistent prenatal care is strongly associated with positive birth outcomes and is a global health priority.¹⁰ However, Pacific Islanders, are less likely to receive early and consistent prenatal care compared to other racial/ethnic groups and are thus at a higher risk for maternal and infant health disparities.^{3,4,11}

Pilot analysis of Arkansas birth records (n=2,488) has shown that Marshallese in Arkansas experience a high rate of adverse perinatal outcomes: 15% of Marshallese women received no prenatal care (compared to 1.6% women nationally); More than 50% do not attend the recommended number of prenatal care visits; 19% of Marshallese infants were born preterm (compared to 9.6% nationally), and 15% of Marshallese infants were low birthweight (compared to 8.3% nationally).¹² Additionally, qualitative data, demonstrate that Marshallese women experience numerous structural barriers that constrain prenatal care such as negotiating health insurance, transportation, and language barriers. Social-cultural barriers include a lack of understanding of the importance of seeking early and consistent prenatal care, feelings of shame and embarrassment, perceived discrimination from prenatal care providers, and an overall fear of the process.¹¹

Current health care interventions are not culturally relevant or focus primarily on individual-level motivations that are not effective within highly collectivistic Pacific Islander cultures.^{13,14} Pacific Islander communities' concepts of health and wellbeing are largely shaped by collectivistic cultural values and practices, suggesting the need for culturally adapted group-based interventions.¹⁵ Recent data with other cultural groups report that pregnant women who received a group-based prenatal intervention (Centering Pregnancy) had a significantly lower risk of having a preterm birth, low birth weight infants, and improved outcomes with GDM compared to women receiving individualized care.¹⁶⁻²² However, group prenatal care has not been culturally adapted and tested with the Marshallese or other Pacific Islanders in the mainland US.

From 2000 to 2010, the Pacific Islander population in the US increased by 40%, growing three times faster than the total US population and making it the second-

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fastest-growing population in the US. The fastest growth occurred in the South (66%), especially in Arkansas (252%), where the majority of Pacific Islanders are Marshallese.²³ Arkansas has the largest population of Marshallese living in the continental US (~14,000 people).²⁴⁻²⁸ Since the Pacific Islander population is small, some argue that the Pacific Islander population should be given less consideration for funding than other racial and ethnic groups; this faulty logic has directly contributed to the stark health disparities experienced by this population. Pacific Islanders are underrepresented in research and receive far less investment than other disparate populations (both in total and in proportion to their population numbers).²⁹⁻³⁴ Overall, limited scientific knowledge, masked health disparities due to data aggregation of Pacific Islanders with other Asian groups, and a lack of resource allocation for research and programs are critical barriers to progress in addressing Pacific Islanders' health disparities.³¹⁻³⁴

To design a culturally appropriate group prenatal intervention among Marshallese and other Pacific Islanders in the US, it is necessary to understand Marshallese culture and the historical relationship between the Republic of the Marshall Islands (RMI) and the US. Between 1946 and 1958, the US tested nuclear weapons in the Marshall Islands. Tests were equivalent to 7,200 Hiroshima-sized bombs and exposed islanders to significant levels of nuclear radiation.³⁵⁻³⁸ After the nuclear tests, US scientists set up Project 4.1 to study the effects of nuclear radiation on humans.³⁹⁻⁴² The research was conducted without informed consent and without language translation.³⁸ Studies demonstrate health problems affecting those exposed and changes in Marshallese health behaviors.⁴³⁻⁴⁶ Like other cultures marked by historical trauma, the Marshallese exhibit distrust in researchers.⁴⁷ The research team is overcoming this historical trauma through the use of a community-engaged research (CER) approach.^{48,49} CER shares power and builds trust between academic researchers and the community.^{50,51} The research is based on an academic-community partnership between the University of Arkansas for Medical Sciences (UAMS) and the Marshallese community.⁵²⁻⁵⁴ The historical trauma makes the use of a CER approach key to the proposed research. Furthermore, there is evidence that utilizing behavioral interventions validated in one Pacific Islander group can be effective in other Pacific Islander populations. Establishing the evidence-base for interventions designed for Pacific Islanders may also inform work with other disenfranchised and indigenous populations who have strong collectivist cultures, thus increasing the generalizability of the proposed research.⁵⁵⁻⁵⁹

The purpose of the study is to culturally adapt and examine the feasibility of a group prenatal program (Kömmour Prenatal) to reduce maternal and infant health disparities among Marshallese women in the US. The word "kömmour" signifies a healthy birth or a

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healthy start in the Marshallese language and was the name chose by the Marshallese advisory board for this study.

Specific Aims

Aim 1: Adapt a group-based prenatal intervention for pregnant Marshallese mothers (Kōmmour Prenatal) through culturally adapting an evidence-based prenatal intervention (Centering).

Aim 2: Conduct a feasibility/pilot test of Kōmmour Prenatal with up to 100 pregnant Marshallese women in Arkansas.

Aim 3: Compare the effectiveness on maternal and infant health outcomes between up to 100 pregnant Marshallese women provided Kōmmour Prenatal with the maternal and infant health outcomes of up to 100 pregnant Marshallese women who received individualized prenatal care. The provision of Kōmmour Prenatal is expected to demonstrate improved primary outcome of Gestational Weight Gain (GWG) and secondary outcomes of breastfeeding initiation; birthweight of infant, preeclampsia; primary cesarean birth; and GDM.

Aim 4: Explore the barriers and facilitators experienced by Clinical Staff and Marshallese Stakeholders who participate in the implementation of Kōmmour Prenatal with Marshallese women in Arkansas.

Study Design and Procedures

A mixed methods design will be utilized to explore the feasibility and preliminary effectiveness of Kōmmour Prenatal among pregnant Marshallese women. Potential participants may be recruited from UAMS centering programs, including mobile centering, across the state.

Participants will be invited to take part in a focus group and survey prior to attending up to 10 group prenatal sessions (Kōmmour Prenatal). Participants will also be invited to take part in both the survey and qualitative focus groups at the end of the intervention. The surveys will capture demographics, health behavior and health belief information. The focus groups will focus on beliefs and experiences of individualized and group prenatal care, prenatal care satisfaction, and health behaviors. Study procedures (e.g., consent process, focus groups, surveys, data collection, administering compensation) will be conducted in person or remotely. In either case, tools such as phone, video, email, text, and online data collection tools (e.g., REDCap) may be used.

Due to difficulty with in-person data collection, remote data collection via Zoom will be utilized to collect focus groups and surveys when in-person data collection is not feasible for the participant.

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To reduce the participant burden, information regarding birth and/or death outcomes and other variables may be collected up to 7 years post-delivery and linked to the participant and her child(ren) from one of the following sources: (1) the mother's electronic medical record at UAMS; (2) the Arkansas Department of Health (ADH) birth and/or death records; (3) the Arkansas All Payers Claims Database (APCD); or (4) via a release of information signed by the mother for babies delivered outside of UAMS. The consent document will include consent for each of these sources. Data collected from these sources may include: general contact and background information about (such as name, address, and telephone number), living situation, income, educational background, maternal medical history, and birth outcomes (gestational age, birth weight, complications, etc). A complete list of data that may be collected from the ADH is attached to this protocol in Appendix 1. Participants will be asked to acknowledge their understanding of this data collection at the time of consent. Participants will have the opportunity to choose if they wish to be re-contacted for future research at the time of consent.

In addition, data from this study will be linked to vital birth record information from the Arkansas Department of Health. Participants will be asked to acknowledge their understanding of this data collection at the time of consent. Data collected from the Arkansas Department of Health may include, but is not limited to: demographic and socioeconomic information, maternal medical history, and birth outcomes (gestational age, birth weight, complications, etc). Because data from birth records is aggregated, data from the Arkansas Department of Health will provide disaggregated data so that covariates (demographic and socioeconomic variables) can be used in the analyses.

Participants will have the opportunity to choose if they wish to be re-contacted for future research at the time of consent.

We will collect the following information via medical record abstraction:

For Marshallese participants who are pregnant:

- date of first prenatal care visit
- number of prenatal care visits
- fasting glucose
- weight and height
- blood pressure
- gestational weeks at delivery
- complications

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- gestational diabetes mellitus
- infant feeding intentions

For infants of Marshallese participants

- date of birth
- size of infant
- weight and height
- complications

Participants will be given the opportunity to separately consent to allowing investigators to link their data to the Arkansas All-Payer Claims Database (APCD). For those participants that provide consent, investigators will analyze the cost of participants care relative to their risk factors. The research team may analyze outcomes across multiple studies if participants provide permission in the consent process.

Qualitative data will be collected from up to 100 participants in focus groups. A semi-structured focus group guide will be used to allow participants to speak in-depth about their health beliefs and experiences, yet also ensure that all focus groups cover the same topics. The focus group guides were developed in partnership with community-based participatory research (CBPR) stakeholders and from information gained through fieldwork. Focus groups will have an anticipated duration of one hour.

In addition, we will collect data from up to 10 clinical staff and/or Marshallese stakeholders who participated in the implementation of the group prenatal program for Marshallese women. Clinical staff and/or Marshallese stakeholders will participate in one individual interview and one demographic survey. Data collection will take place at the end of the interventions duration.

Study Schedule for women in Kōmmour Prenatal

For pregnant women enrolled in Kōmmour Prenatal, the first survey and focus group will take place at enrollment. Participants will attend up to 10 group prenatal sessions. Another survey and focus group will take place in the third trimester (6-9 months of pregnancy). Data abstraction from birth and medical records will take place after the birth for information of both the postpartum participant and her infant.

Data Collection-Pregnant Women in Kōmmour Prenatal
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Enroll	First trimester	Second Trimester	Third trimester	Six Weeks Postpartum
Enrolled in study	X	X	X	
10 Group-Prenatal Intervention	X	X	X	
Medical record abstraction	X			X
Birth record abstraction				X
Focus group	X	X	X	
Survey questionnaire	X	X	X	

Study Timeline

Study initiation is planned for January 2021 with a duration of five years (60 months). Focus group guides and survey adaptation will take place in months 1-3. Enrollment will take place in months 4-16. Participants will attend up to 10 group prenatal sessions. The last participant enrolled will have time for final data collection prior to the end of the study at 60 months.

Study Population- Marshallese Pregnant Women

Participants must be female, age 18 or older, pregnant, who are self-reported Marshallese. Up to 100 women and up to 100 infants born to these women will be recruited through a bilingual community health worker and through our relationships with community organizations, specifically the Marshallese Education Initiative (MEI), Arkansas Coalition of Marshallese (ACOM), Marshallese pastors, and other community contacts developed through prior CBPR fieldwork.

Inclusion Criteria

- Female
- 18 years of age or older
- Pregnant
- Self-reported Marshallese

Exclusion Criteria

- Not Self-reported Marshallese

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- Under 18 years of age
- Not pregnant

Study Population-Clinical Staff and Marshallese Stakeholders

Participants must be age 18 or older, clinical staff and/or Marshallese stakeholders who participated in the implementation of a group prenatal program for Marshallese pregnant women.

Inclusion Criteria

- 18 years of age or older
- Self-reported as clinical staff and/or Marshallese stakeholders who participated in the implementation of a group prenatal program for Marshallese pregnant women.

Exclusion Criteria

- Not self-reported as clinical staff and/or Marshallese stakeholders who participated in the implementation of a group prenatal program for Marshallese women.
- Under 18 years of age

Risks and Benefits

There is no direct benefit, but what we learn may help other people in the future. Potential risks to study participants are minimal. There is a potential risk for loss of confidentiality. Potential risks to study participants by allowing access to information related to bills for healthcare services from the Arkansas All-Payer Claims Database are minimal. Measures to protect the confidentiality of study participants will be implemented as described in the Data Handling and Recordkeeping section.

Data Handling and Recordkeeping

The principal investigator will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study. All study subject material will be assigned a unique identifying code or number. The key to the code will be kept in a locked file cabinet in a locked file room in the Office of Community Health and Research. Only the principal investigator and the study coordinator will have access to the code and information that identifies the subject in this study. At the conclusion of the study, the data will be permanently de-identified.

The study will comply with UAMS Admin Guide Policy 3.2.01 – research data, reports and analyses be retained for seven years after final reporting or publication of a project, or longer if required by a sponsor or regulation.

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Data Analysis

Data collection and analysis for Aim 2:

A mixed-methods design will be used to determine the feasibility of Kōmmour Prenatal to improve adherence to recommended prenatal care visits and prenatal care satisfaction. After consent, and prior to the first focus group, participants will be asked to complete a survey. The survey may be completed in person or electronically via a link to REDCap. After participants have completed the survey, we will begin the focus group. Within the focus group, participants will be reminded to not disclose the identity of others who are participating or any information discussed. Focus groups will take place in a private room of a community-based organization- e.g. Jones center, hospital, UAMS-NW, local community church, or remotely using phone or a secure technology such as Zoom or Skype.

After the participants have provided consent and completed their first survey and focus group, participants will begin a series of up to 10 group prenatal sessions (Kōmmour Prenatal).

At third trimester participants will be asked to participate in an additional survey and focus group focused on their experiences in this intervention. Consistent with the first focus group, participants will be reminded to not disclose the identity of others who are participating or any information discussed. Focus groups will take place in a private room of a community-based organization- e.g. Jones center, hospital, UAMS-NW, local community church, or remotely using phone or a secure technology such as Zoom or Skype.

Data collection for Aim 3:

A systematic medical chart review will be used to document the primary outcome of GWG and secondary outcomes of: breastfeeding initiation; birthweight of infant, preeclampsia; primary cesarean birth; and GDM from women enrolled in Kōmmour Prenatal and those in individualized care. Medical chart review data for the up to 100 pregnant Marshallese women who received individualized prenatal care will be from participants in studies previously approved by the UAMS IRB where the participants agreed to their data being used in related studies. Birth record data and the linkage to ADH data will be used to assess maternal and infant health outcomes. It is necessary to use both medical birth record and de-identified data through ADH to receive disaggregated data to identify matching covariates for the analyses. These variables will include maternal age, parity, and sociodemographic variables. Propensity scores will be estimated using the variables available for both the Centering Pregnancy participants and the participants in Dr. McElfish's cohort study. Each Centering Pregnancy participant will be propensity score matched without replacement with a participant in

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the cohort study using a nearest neighbor algorithm. Success of matching will be assessed by comparing covariate balance between groups using both standardized differences in covariate means and graphical displays of group differences. Logistic regression will be used to test for differences in the outcomes between the Centering Parenting and the comparison group. PASS 2020 was used for statistical power analyses. The primary analysis for Aim 3 will be a logistic regression with intervention status predicting a binary outcome.

Remuneration

Each Marshallese pregnant participant will receive a \$40 gift card upon completion of each focus group and survey as a thank-you for their time. A participant could receive up to \$80 in gift cards if they participate in both pre-intervention and post-intervention survey and focus group sessions. Gift cards would only be provided for the focus groups and surveys they complete. Clinical staff and Marshallese stakeholders will be excluded from remuneration.

Ethical Considerations

Potential participants, who meet the inclusion criteria, will be offered the opportunity to join the study. Each participant will be provided a paper and/or electronic copy of the consent in either/both English and Marshallese. The participant will be given time to ask questions. Those who choose to participate will sign the consent form. Only those who provide consent will be included in the intervention and eligible for the surveys and focus groups. Prior to the first focus group, but after consent, participants will be given a questionnaire to collect demographic information. There will also be a HIPAA authorization for medical record and birth record abstraction that the pregnant participants will sign for themselves and their infants. Recruitment, consent, surveys, and focus groups will all take place in the same setting for the participant.

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board (IRB) to conduct the study.

Dissemination of Data

Results of this study may be used for presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant. The study will be listed on clinicaltrials.gov in accordance with (funder and/or journal) requirements. Aggregated results may be returned to participants in an infographic that is provided in person, e-mail and/or mailed to the participants. We will also work with stakeholders to disseminate aggregated information in town hall

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meetings.

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Title: Determine the Preliminary Effectiveness of Mobile CenteringPregnancy to Improve
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Appendix 1

Commented [KS1]: Placeholder

List of variables that may be collected from the Arkansas Department of Health:

Vital Statistics – Birth

Date of Birth (Infant)--Month

Date of Birth (Infant)—Day

Place Where Birth Occurred (type of place or institution)

Mother Married?-- At Conception, at Birth or any Time in Between

Date of First Prenatal Care Visit—Month

Total Number of Prenatal Care Visits

Mother's Height--Feet

Mother's Height—Inches

Mother's Weight at Delivery (in whole pounds)

Previous Live Births Now Living

Risk Factors--Prepregnancy Diabetes Risk Factors--Gestational Diabetes

Risk Factors--Prepregnancy Hypertension

Risk Factors--Gestational Hypertension

Risk Factors--Previous Preterm Births

Risk Factors--Poor Pregnancy Outcomes

Risk Factors--Infertility Treatment

Risk Factors--Previous Cesarean

Characteristics of Labor & Delivery--Meconium Staining

Characteristics of Labor & Delivery--Fetal Intolerance

Characteristics of Labor & Delivery--Anesthesia

Method of Delivery--Attempted Forceps (NCHS DELETED THIS ITEM EFFECTIVE
2011)

Method of Delivery--Attempted Vacuum (NCHS DELETED THIS ITEM EFFECTIVE
2011)

Method of Delivery--Route and Method of Delivery

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Obstetric Estimation of Gestation

Congenital Anomalies of the Newborn--Down Syndrome

Congenital Anomalies of the Newborn--Suspected Chromosomal disorder

Congenital Anomalies of the Newborn—Hypospadias

Was Infant Transferred Within 24 Hours of Delivery? Is Infant Living at Time of Report?

Is Infant Being Breastfed? (RECOMMENDED CHANGE TO "AT DISCHARGE"
EFFECTIVE 2004)

Risk Factors--Hypertension Eclampsia (RECOMMENDED ADDITION EFFECTIVE
2004)

Mother's Age (Calculated)

Mother's Race – Specify

State of Birth FIPS Code (Required)

Verification of height (Mother)

Verification of pre-pregnancy weight

Did mother smoke three months before or during pregnancy? Prenatal care?

Verification of number of prenatal care visits Obstetric procedures - none selected

Medical risk factors - none selected Infection present - none selected

Maternal morbidity - none selected

Characteristics of labor - none selected

Mother transferred in for delivery?

Onset of labor - none selected Weight units

Pounds

Ounces

Plurality

Infant abnormal conditions - none selected