The Challenges of Conducting Research in Rural Populations: A Feasibility Study

Kirsten E. Hepburn, RN[1]

Katrina Poppert Cordts, PhD[2]

Dinkel Danae, PhD[3]

Alyson Hanish, PhD, MSN, RN[4]

Gurudutt Pendyala, PhD[5]

Tiffany A. Moore, PhD, RN, SANE-A[6 *]

[1] PhD Student and Graduate Assistant, College of Nursing, University of Nebraska Medical Center, kirsten.hepburn@unmc.edu

[2] Assistant Professor, Department of Neurological Sciences, University of Nebraska Medical Center, katrina.cordts@unmc.edu

[3] Assistant Professor, School of Health & Kinesiology, University of Nebraska at Omaha, dmdinkel@unomaha.edu

[4] Assistant Professor, College of Nursing, University of Nebraska Medical Center, alyson.hanish@unmc.edu

[5] Associate Professor, Department of Anesthesiology, Child Health Research Institute, and National Strategic Research Institute, University of Nebraska Medical Center, gpendyala@unmc.edu

[6] Associate Professor, College of Nursing, University of Nebraska Medical Center, tamoore@unmc.edu

*Correspondence: Tiffany A. Moore

Abstract

Purpose: Chronic stress related to health disparities results in negative health outcomes for mothers and infants. The brain-gut-immune axis plays a significant role in perinatal health outcomes. Researchers have not focused on the effects of rural living on the maternal/infant gut microbiome. The purpose of our study was to validate recruitment protocols, data and specimen collection protocols, participant feedback, and participant retention strategies for future studies in a rural Nebraska population of mother/infant dyads.

Sample: Mother/infant dyads living in Nebraska counties with a rural-urban commuting area (RUCA) code of three or greater (n = 17 dyads, n = 1 triad).

Methods: We conducted a cross-sectional pilot feasibility study by collecting stool samples, actigraph data, sleep diaries, and health and lifestyle questionnaires from mother/infant dyads living in rural Nebraska counties.

Findings: Retrospective review of this pilot study identified the main feasibility findings were primarily related to distance: 1) relying on virtual recruiting methods was cost-effective; 2) stool sample shelf-life created participant inconvenience; 3) shipping carrier delays affected collection timing of actigraph data; 4) participant access to shipping carrier drop-offs increased cost and inconvenience.

Conclusion: Rural locations create barriers to research, but none are insurmountable. When working with rural populations, it is important to consider the potential adaptation of participant recruitment methods and protocol procedures, including careful attention to shipping and related time constraints that may impact data collection.

Keywords: rural recruitment, maternal/infant, microbiome

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Chronic stress related to health disparities disproportionately affects rural populations, resulting in adverse health outcomes for some rural mothers and infants (Amjad et al., 2019). The brain-gut-immune axis plays a significant role in the interplay between biological, psychological, and environmental influences and perinatal health outcomes (Kan et al., 2019). Very little research focuses on the effects of rural living on the maternal/infant gut microbiome. To fill this gap, we piloted a study to test the feasibility of recruiting mother/infant dyads from rural counties in Nebraska, a preliminary step for a larger study aimed at examining maternal risk factors that may influence the brain-gut-immune axis and impact infant/child development in rural populations.

A rural lifestyle has unique stressors that influence certain health outcomes (Liu et al., 2017; Thomas et al., 2014). Drought, pesticide exposure, financial pressure, climate variability, poor physical health, and past injuries can increase the risk of mental health disorders in rural workers (Batterham et al., 2022; Daghagh Yazd et al., 2019). Rural counties have higher excess deaths from heart disease, cancer, unintentional injury, stroke, and chronic lower respiratory disease (Garcia et al., 2019). It is unknown how disparities in rural health influence modifiable factors that alter the microbiome, such as stress, substance use, sleep, diet, and activity, while concurrently affecting the maternal and infant microbiome and childhood development. Understanding these relationships within the rural population could lead to early screening and intervention, but little evidence exists regarding how these interactions affect the microbiome and health outcomes. One method of assessing health and the brain-gut-immune axis is to study the gut microbiome (Sylvia & Demas, 2018). The microbiome consists of non-human organisms, primarily bacteria, living on and inside the body that heavily influence overall health (Proctor et al., 2019). A mother likely

passes her microbiome on to her baby during pregnancy, possibly affecting the child's development and health outcomes (Mesa et al., 2020).

Nebraska is sparsely populated, covering 77,000 square miles with 25.5 people per square mile (United States Department of Agriculture [USDA, n.d.-a)]. The U.S. Department of Agriculture classifies most of the state's counties (86%) as "nonmetro" (USDA, n.d.-a). Nebraska's geodemographic makeup makes it an ideal setting for studying the effect of stress risk factors on the brain-gut-immune axis and infant/child development. This study's interdisciplinary team was primarily based in Omaha, Nebraska's largest metro area. Participants were spread across the rural parts of the state, with the average distance between a participant and the University of Nebraska Medical Center (UNMC) being 183.9 miles (range 30 to 297 miles).

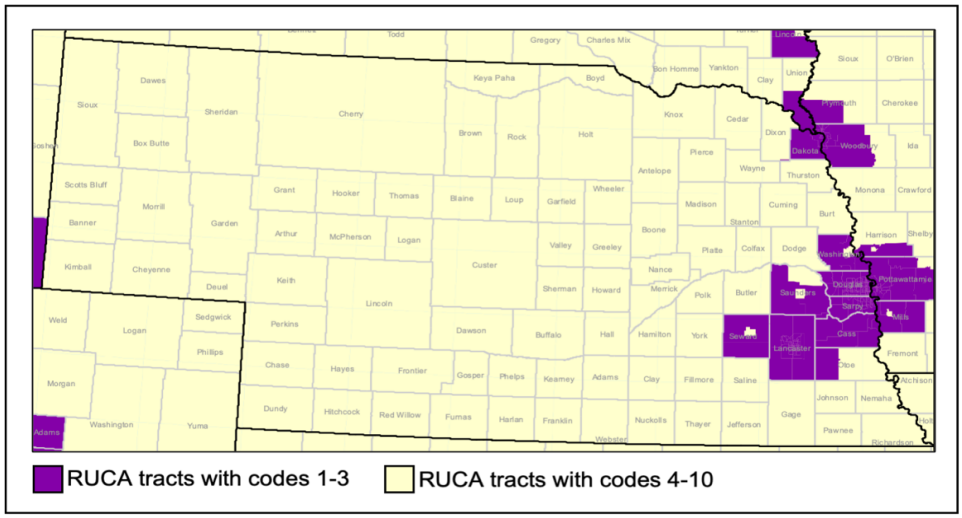
Few studies in the literature describe recruiting, data collection, and participant feedback in rural areas in the United States. However, previous research indicated barriers were possible, such as those related to distance, incentive, or motivation to participate, and complexity of study materials (Friedman et al., 2015; Miyamoto et al., 2013). Recognizing those potential barriers, our study aimed to validate recruitment protocols, data and specimen collection protocols, and collect participant feedback to support retention strategies for a future larger grant proposal in identifying associations between rural lifestyle factors and the gut microbiome of rural mother/infant dyads. Our pilot study identified an overarching feasibility consideration related to the distance between participants and the study team. Four subpoints were noted: 1) reliance on virtual recruiting methods; 2) stool sample shelf life; 3) actigraph data collection timing; and 4) shipping carrier access.

Methods

Following approval from the Institutional Review Board at the UNMC, mother/infant dyads living in Nebraska counties with a rural-urban commuting area (RUCA) code of greater than three were targeted for inclusion (Figure 1) (USDA, n.d.-b). Consent was obtained via a 15-minute phone call describing the study, including risks/benefits. Identifiers were removed from their data and stored on password-protected servers to protect participants' privacyU. Study participants (n = 17 dyads, n = 1 triad) completed online questionnaires measuring activity, sleep, stress, and diet via REDCap (Harris et al., 2019) and collected stool samples once. Participants also wore an actigraph for one week. The actigraph, an electronic monitor worn continuously like a wristwatch, collected sleep and activity data based on their movement. Participants were instructed to remove the actigraph while bathing or swimming.

Figure 1

Rural definition based on Economic Research Service Rural-Urban Commuting Areas (RUCA) in Nebraska



(https://www.ers.usda.gov/). In the public domain.

Mothers filled out questionnaires about their baby's development, had their baby wear an actigraph for a week, and collected one stool sample from their baby. Participants were compensated $25 for survey completion, $25 for stool sample collection, and $50 for actigraph use. In their package of study materials, participants received a printed feedback questionnaire with a postage-paid return envelope allowing them to submit their answers anonymously. The questionnaire asked participants to use Likert scale ratings to report their experiences with taking the surveys, stool sample collection, the activity monitors, and general feedback. The questionnaire also had space for participants to provide written details and feedback. Half of the participants (n=9) returned their feedback questionnaire.

Results

Virtual Recruiting Methods

Our goal was to recruit 20 mother/infant dyads. Physical distance created barriers to in-person recruiting, thus social media was used. Using Facebook, we ran three rounds of study advertisements (ad) targeting rural women in Nebraska. Facebook offers paid advertising space, which places the ad in the margin of our targeted demographic's Facebook news feeds (Image 1).

Image 1

Screenshot of Facebook advertisement for the study.

The image of the ad was also posted once on UNMC's Facebook page, which, as of July 2023, has 25,000 followers. An interested participant could contact the study via the email or phone number listed in the ad. The first round created the most contacts, yielding 16 inquiries and generating nine consented participants. The second round produced nine inquiries which yielded nine consented participants. The third round yielded one inquirer who did not meet the study criteria. In total, 18 participants were successfully recruited via Facebook. The overall cost of targeted Facebook advertising was approximately $250, equating to just under $14 per participant.

Stool Sample Shelf Life

Stool sample collection supplies were acquired from DNA Genotek, Inc. as a pre-packaged kit (Image 2) (DNA Genotek, 2022). Each kit contained user instructions, a small plastic spatula,

Image 2

OMNIgene-GUT collection kit from DNA Genotek, Inc.

Note. Image reprinted with permission from DNA Genotek, Inc.

A bio-specimen bag, one vial containing a small amount of ethyl alcohol and a metal agitator ball, and two toilet accessories for catching stool. Additional vials and spatulas were ordered from DNA Genotek to provide enough vials to obtain microbiome and metabolomic samples from mother and baby. Participants received a total of four vials, two for metabolomics samples (OMNImet·GUT®) and two for microbiome samples (OMNIgene·GUT®). The mother collected one of each for herself and her baby. Each kit also included pre-addressed return mailers, two pairs of nitrile gloves, and a water-resistant paper sheet (13x18”) for quick and easy collection and cleanup. Each kit, including the additional tubes and shipping from the manufacturer to UNMC, cost approximately $75 per dyad. Additional packing and shipping materials added approximately $13 to each kit, bringing the total stool sample supplies cost to about $88/dyad.

Selecting stool sample collection kits for rural participants required consideration of the samples' shelf-life following collection. At room temperature, the metabolomic samples are stable for seven days, and the microbiome samples for 60 days. The collection tubes were returned together. Sample arrival at the lab for processing or storage within seven days of the collection was an important consideration. Participants were instructed to collect their samples on Sunday-Wednesday and send them no more than 24 hours after collection (same-day collection and mailing were strongly encouraged). Two-day return shipping method was utilized to ensure the samples would reach the lab within the desired time frame.

Aside from expressing concern about returning stool samples to Omaha on time, some participants reached out to researchers via phone or email to also ask questions regarding the stool sample collection. Questions included concerns about the potential impact of antibiotic usage on study outcomes, liquid spillage from the tube while trying to scoop stool, and if stool samples could be collected outside the timeframe the baby was wearing the actigraph as the baby only had bowel movements at daycare that week when the mother could not collect a sample. One participant's feedback form included the comment, "….being rural the stool sample return was a little stressful."

Actigraphs

Participants were asked to wear an actigraph and place one on their baby to collect sleep and activity data for seven consecutive days. Phillips Respironics Actiwatch Spectrum wristwatch devices were available for study use. The back of the actigraph must be in contact with the skin to collect data and beeps when it is not. The actigraphs could be programmed to start and stop gathering data at a future time, which was helpful to protect battery life and minimize beeping while in the mail. The challenge this presented was ensuring the actigraph would reach the

participant before the pre-programmed data collection start time without sacrificing battery life. Initially, the actigraphs were sent with a signature requirement, given the replacement cost (approximately $750/device). However, this practice was discontinued because packages were not delivered without a signature, delaying start times if a participant was not home at the time of delivery and resulting in partial data from those participants.

The actigraphs were modified to make them wearable by a baby. The manufacturer's band was removed, and a white sweatband was used instead. Participants were instructed to place the actigraph on the baby's ankle or thigh, depending on their size (Image 2; Dinkel, 2022). For the actigraph to work, a slit was cut in the seam of the sweatband, allowing the back to be positioned next to the baby's skin. Without a barrier between the baby's skin and the actigraph, participants were instructed to check it often throughout the day and discontinue use at any sign of irritation or discomfort.

The most common complaints on feedback forms were that a white sweatband showed dirt quickly, and the actigraph left marks on the baby's skin. One participant commented, "Baby's [actigraph] dislodged easily and eventually fell out of the soft sleeve easily. I feel there needs to be a better way to secure to baby." Some participants discontinued actigraph use on their baby after a few days (n = 4). About half of the babies (n = 10) and most mothers (n = 15) wore the actigraphs long enough to produce useful data. Mothers were also asked to keep a sleep diary for

Image 2

Actigraph placement on baby's ankle.

Note. Image used with permission. (© Dinkel, 2022)

themselves and their babies to aid in data analysis.

Shipping

The primary shipping carriers in Nebraska are the United States Postal Service (USPS), United Postal Service, and Federal Express (FedEx). Although the USPS has the most locations and delivers to every officially recognized address in the United States, delivery speed was the most important consideration in this study. FedEx's two-day air shipping was selected as the primary carrier and shipping method. When returning study materials, participants were asked to drop off return envelopes at a FedEx location to minimize study costs (i.e., additional fees were

incurred for FedEx at-home pick-up from participants). When participants did not have ready access to a FedEx drop-off location, they called to schedule an at-home pick-up. Participants sometimes experienced delays and inconvenience when returning materials (e.g., the nearest FedEx drop-off location, operating inside a Dollar General store, could only scan FedEx Ground labels, not the FedEx Air labels utilized in this study). The shipping cost to and from rural participants ranged from $11.88 to $37.55 per shipment each way.

Discussion

While conducting a pilot study to investigate the potential barriers to studying the effect of stress and risk factors on the microbiome and subsequent growth and developmental outcomes in rural mother/child dyads, the distance between the participants and the investigatory team was the primary feasibility consideration. More specifically, this includes addressing factors related to virtual recruitment methods, stool sample shelf life, actigraph data collection, and shipping carrier access. Pribulick et al. (2010) cite the expenditures of money and time related to in-person rural recruitment as a significant barrier to their research on the cardiovascular health of rural women in 2006. Their large study team made multiple trips, traveling up to 16 hours on two-lane roads in rented vans, and stayed overnight in some communities to recruit the 117 participants.

Nowadays, the ubiquitous nature of social media provides access to potential study participants from a distance at a low cost and minimal time investment. Our study found targeted advertising on Facebook to be a cost-effective recruiting method ($14 per participant). However, interest waned by the third run of ads, indicating that additional social media platforms or other means of online advertising may be necessary to garner increased participant interest for a larger sample in the future. Kim et al. (2021) found that passive advertisement (i.e., posting study flyer photos to a local group's newsfeed) in rural Facebook groups was unsuccessful. The researchers

cited a lack of access to local groups that require a historical or familial link to the area to gain entry and low trust or knowledge of the researchers as possible reasons for the inability to recruit via this method (Kim et al., 2021). In the future, our study will focus on expanded targeted online advertising and identifying local rural health clinics that would serve as champions for the research study for recruitment purposes.

In this study, stool sample shelf life was a concern in the context of conducting research at a distance. Although self-collected specimens for testing are becoming commonplace, like mail-in occult fecal blood tests, no studies address the logistics of collecting larger stool samples from a distance (Tenover et al., 2017). Therefore, using a commercial supplier for the stool collection kits simplified the collection process and provided a protocol for the shelf life of samples. During the consent process, participants were told that they would need to coordinate their sample collection and shipping to ensure the samples' timely arrival at the lab to preserve sample shelf life. One participant who lived in an area without a nearby FedEx drop-off location was worried about delay rendering her stool samples unusable, so she offered to drive her stool sample more than 60 miles to ensure timely arrival to our lab. Rather than create undue stress and inconvenience for her, she was instructed to call FedEx to schedule an at-home pick-up and reassured that her data was still valuable to our study.

Rural dwellers perceive distance as a significant barrier to their healthcare, including a lack of convenient access to laboratory and clinic sites (Buzza et al., 2011). Knowing this, our study sought to ease this burden by using self-collected stool samples that could be shipped directly back to the research team using a nearby FedEx drop-off location rather than going to a clinic or laboratory for sample collection. However, due to the sparseness in FedEx drop-off locations in some rural areas, our participants did not all have convenient access to one. FedEx will go to a

home location for a scheduled pick-up for a fee, which increases with the home's distance from a centralized FedEx hub. Asking rural participants to drop off their study supplies can inconvenience the study participation experience, possibly decreasing interest in participation. It may be beneficial to allocate special funding to pay for the additional cost of at-home scheduled pick-ups to minimize inconvenience for participants.

Most of the participant's complaints were related to the actigraphs. Participants expressed displeasure at the marks the actigraphs left on the baby's skin which was the primary reason for discontinuance. The white band showed dirt easily; a second band to switch out for washing or using a darker color might reduce complaints. In the future, alternatives to monitoring the baby's sleep and activity may be necessary. Currently, there are no available alternative actigraphs that are designed specifically for use on infants. However, some accelerometers do not require direct skin contact like the model used in our study, which would allow a barrier between the infant's skin and the actigraph, reducing the chance of marks and possibly improving adherence in future studies.

Research Implications

Rural locations create barriers to research, but none that are insurmountable. Overall, participants were quite willing to problem-solve and look past some of the challenges encountered during this pilot study. Future research considerations should include creative recruitment strategies when the research team is not local, shipping/handling considerations, and innovative data collection methods that decrease the burden on participants.

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Conflicts of Interest

These authors declare no conflicts of interest.

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