PROTOCOL TITLE:

Effects of the COVID-19 Health Emergency on the Biopsychosocial Health of Rural Residents of New Mexico using Mixed Methods

PRINCIPAL INVESTIGATOR(s):

Carla S. Wilhite, DOT, OTR/L FAOTA

Department of Pediatrics

Co-Principal Investigators:

Timothy Dionne, PhD, OTR/L

Janet L. Poole, PhD, OTR/L FAOTA

ADMINISTRATIVE CONTACT:

Sylvia Nolasco, Division Administrator

Department of Pediatrics-Division of Occupational Therapy

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REGULATORY FRAMEWORK:

Please indicate all that apply:

☐	DOD (Department of Defense)
☐	DOE (Department of Energy)
☐	DOJ (Department of Justice)
☐	ED (Department of Education)
☐	EPA (Environmental Protection Agency)
☐	FDA (Food and Drug Administration)
☐	HHS (Department of Health and Human Services)
☐	VA
x	Other: NIH

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CLINICAL TRIALS

Is this a clinical trial per the NIH definition of a Clinical Trial? ☐ Yes ☒ No

NIH Definition of a Clinical Trial:

A research study in which one or more human subjects are prospectively assigned to one or more interventions. An "intervention" is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Use the following four questions to determine the difference between a clinical study and a clinical trial:

1) Does the study involve human participants? ☒ Yes ☐ No
2) Are the participants prospectively assigned to an intervention? ☐ Yes ☒ No
3) Is the study designed to evaluate the effect of the intervention on the participants? ☐ Yes ☒ No
4) Is the effect being evaluated a health-related biomedical or behavioral outcome? ☒ Yes ☐ No

Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if…

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention

If yes to all 4 questions, please confirm that the research team is familiar with and agrees to comply with the investigator requirement to register the study on the ClinicalTrials.gov database. Additionally, the approved consent document(s) must be uploaded to the ClinicalTrials.gov database ☒ Yes ☐ No

For any assistance with registration of your trial or the requirements, please contact HSC-CTSCResearchConcierge@salud.unm.edu

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1. Objectives

Purpose: The purpose of the research is to determine how people residing in New Mexico counties and cities are experiencing the phenomenology of the COVID-19 pandemic and a rating of quality of life. The specific questions of interest are:
1. How are rural-living vs. urban-living people responding physically and mentally to the crisis?
2. What strategies of resilience are employed by people living in rural vs. urban counties?
3. What are perceptions of access to critical supplies and services in urban vs. rural counties;
4. How is the availability and use of technology used for news, reliable information, and communication? And;
5. What alterations in daily life self-care, care of others, commerce, and valued routines in urban vs. rural counties are occurring?

There is a critical need to determine the impact of the COVID-19 emergency on the comprehensive well-being of people as they are living through the emergency and the extended sequelae of the emergency period.

Specific Aims:

Aim 1: Extensively evaluate the perceived quality of life (QOL) of urban vs. rural living people during the COVID-19 emergency, thereby assessing similarities and differences in QOL impact during the national health emergency.

Aim 2: Evaluate the daily lived experience of people living in rural and urban areas during the health emergency in regard to biopsychosocial factors impacting the well-being of individuals and families, including access to services and resources for health, finances, technology, news and information use, use of time, and psychosocial support.

Aim 3: Determining use of resilience strategies (protective factors) of urban vs. rural living people during the national health emergency.

Hypothesis

Rural-living people experience the health emergency with a significant impact to well-being (physical, psychological, and social) as compared to urban people.

2. Background

The state of New Mexico and the entire nation have entered an *unprecedented health emergency* created by the COVID-19 virus; affecting the lives of all people, many of whom were significantly unprepared for the disruptions the emergency created in daily life. *Rural residents are at increased risk* from effects of the emergency due to numerous disadvantages as compared to urban living people (i.e. critical care access, food insecurity, social isolation). Very little is known about how people are living through a national emergency event affecting *all people* of the nation. Therefore, a *significant gap* in knowledge exists:

Preliminary research from China on mental health and quality of life during the COVID-19 emergency (Zhang & Ma, 2020; Wang, et al. 2020) find mixed results. Zhang (2020) reports the pandemic as a mild stressful impact, although 52.1% (N=263) of respondents

in one city also felt “horrified and apprehensive” due to the pandemic; however Wang et al. (2020), found over 50% of respondents (N=1210) from 194 cities were experiencing moderate to severe psychological effects of the pandemic.

Although there are no peer reviewed published studies in the United States at this time, the Henry J. Kaiser Family Foundation issued a briefing from a Kaiser poll indicating that 45% of adults in the U.S. have reported their mental health has been negatively impacted due to worry and stress over the virus, and noting those living in social isolation and low income may be disproportionately affected by the health emergency. One study on people living in the United States with rheumatic diseases (N=530) reported stresses and anxiety/fear/worry over access to medications, health care, sadness and loneliness with social distancing (Michaud, et al., 2020). Additionally, multiple mental health information links are now prominent on the Centers for Disease Control website, indicative of the severity of the mental health impact of the pandemic.

Completion of the research acquires new knowledge in the field on how people have experienced a national emergency and thus, is innovative. As an outcome, the knowledge will be utilized by those who have roles in developing national and community responses to improve planning and preparation for future national health emergencies. As a result, rural and urban-living stakeholders and those in governance will be better informed when making decisions to ameliorate the risk-factors and disproportionate burden of national emergencies affecting access to critical supplies, services, and commerce. The research will be replicable in the region and nation.

3. Study Design

The exploratory research will be conducted using mixed methods: qualitative and quantitative approaches. The quantitative approach incorporates demographic information and a valid and reliable health quality of life measure from the World Health Organization (WHOQOL-BREF) used with permission. The WHOQOL-BREF is 26 question instrument measuring perceptions of physical, psychological, social, and environmental health. Responses can be compared between subject cohorts for specific characteristics, correlations, and effects. The qualitative approach incorporates a researcher developed open-ended semi-structured interview instrument gauged to study the phenomenology of how people in urban vs. rural contexts are experiencing the COVID-19 pandemic.

None of the investigators will be blinded during the investigation.

4. Inclusion and Exclusion Criteria

Inclusion Criteria: Adult residents of New Mexico of any gender, gender identity, and ethnic origin speaking the English language, living in rural or urban/suburban locations, ages 18-85, will be eligible to participate in the study. Screening for eligibility will occur at time of making contact. Pregnant women are not excluded from participation because this special status is not relevant, the research poses less than minimal risk, and pregnancy is not the focus of the study.

Exclusion: Incarcerated individuals, children, and those with inability to give consent will be excluded from the study. Assessing the capacity of consent of the person is limited due to the method of surveying by telephone or internet. The investigators will endeavor to ensure ability to consent by questioning the potential subject about their understanding of the research, their understanding of the right to consent or withdraw (i.e. understanding choice), their ability to reason, clarity in decision-making, and noticing confusion by the potential participant, or noticing cues of impairment (i.e. difficulty with orienting to temporal events, days, months). Investigators will be familiar with principles of competency for consent including items from the MacArthur Competency Assessment Tool for Clinical Research (MacCAT-CR).

Residents of New Mexico may be excluded if they are unable to speak English since the WHOQOL-BREF may not be available in other languages of the resident. The researchers will be preparing for future research using Spanish translations, but will not be modifying the protocol at this time in order to be timely in gathering the urgent data.

Number of Subjects

Up to 300 participants (150 in each group: urban or rural) will be recruited to take the WHOQOL-BREF. The qualitative interview will continue until saturation is reached, not to exceed 300 interviews. The sample is adequate to power the study to reach a power of 0.8.

5. Study Timelines

Consented participants will be enrolled in the study until April 30, 2021 at which time the study will be closed to enrollment. Participants will be given a WHOQOL-BREF survey twice during the health emergency, anticipating timing to be once during the emergency and once post-emergency. Analysis of de-identified collected data will continue after April 30, 2021 to complete statistical operations and preparation of manuscripts.

6. Study Endpoints

The primary study endpoint will occur by April 30, 2021 at the end of the grant funding.

Research Setting

This is a prospective study. Research will be conducted via telephonic or wireless technologies enabling individual contact with prospective participants. Researchers will be based in HSC offices or, from work at home locations as determined by the HSC as necessary due to the pandemic. Prospective participants will be reached via public directories available across every New Mexico county.

7. Resources Available

Dr. Janet Poole is well qualified to direct the study as a principal investigator. She has been a principal investigator on collaborative multi-center, multi-state federal grants

including those from the Patient Centered-Outcome Research Institute. *She has significant experience in conducting UNM approved and indigenous IRB approved research on the Navajo Nation regarding impact of arthritis.*

Co-Investigator Dr. Carla Wilhite has previous IRB approved research experience on disability in agriculture and quality of life of farmers and ranchers with health conditions. She is very knowledgeable about rural health issues of New Mexico communities.

Co-Investigator Dr. Timothy Dionne, has previous IRB approved research experience in rehabilitation and interventional technologies.

To Be Determined: Research Coordinator: The team will hire a research coordinator to assist with adhering to timeline, facilitating filing of interim and final reports, monitoring budget with the assistance of the OT Division Administrative Manager, and other administrative responsibilities. The Research Coordinator will not be handling identifiable information of participants

Four Occupational Therapy Graduate Students who have completed HIPAA & CITI training will assist with collection of data. They will be trained in the appropriate use of screenings, eligibility criteria, and collection tools.

The research team anticipates a 20 hour a week effort (all team members combined) to contact potential research participants for up to 48 weeks. Approximately300 participants are needed to achieve sufficient power for the study.

No dedicated offices or laboratories will be necessary to complete the research.

8. Prior Approvals

This study is registered with the National Institutes Clinical Trials registry.

No radiation will be used in the study, no animals will be used in the study, and no biological specimens are being collected.

9. Multi-Site Research

N/A

10.Study Procedures

Contact information for accessible prospective participants will be derived from publicly available directories for the 33 counties of New Mexico. The research team will be attempting to obtain a representative sample of all New Mexico residents using proportional systematic sampling with a random start point, and a sampling interval of 10, to make contact via telephonic or internet technologies. The goal is to obtain a probability sample for residents by age, gender, ethnicity, and geographic distribution into two cohorts: urban and rural residents. It is desirable to generate a sample that closely mirrors the population of New Mexico.

Researchers making contact will use a contact script to introduce themselves, the purpose of the research, and determine the interest of the person in participating. If a person is

interested in participating a screening for eligibility will be conducted. Once the screening is complete and eligibility is determined, an informed consent process will follow. The consent process will describe the research and the rights of the participant to participate or withdraw from the study. The prospect will be advised the interview will be recorded using a hand-held digital recorder with a phone audio pickup. If consent is obtained verbally, the collection of data will commence. A copy of the consent will be delivered to the participant via U.S. post, facsimile, or electronically.

Demographic data: name, address, county, preferred contact phone and/or email, age, gender/gender identity, education level, socio-economic status, and ethnicity. (see demographic data intake form).

Assessments: WHOQOL-BREF (see attached) 27 item survey questions will be read to the subject and response recorded. The WHOQOL-BREF measures the biopsychosocial perceptions of individuals about quality of life. A semi-structured interview will follow that will ask questions about the emergency experience of the COVID-19 health emergency regarding perceptions of daily life routines, availability of needed resources, and preferred sources of information regarding COVID-19. (See semi-structured interview form).

Once the assessment data is obtained, the subject will be thanked and then invited to participate in a post-event data collection using the WHOQOL-BREF and interest in participating in a focus group at a future time.

Post-event assessment: WHOQOL-BREF. Prior to the conclusion of the study, participants will be asked to perform a post-event assessment of quality of life.

Focus group: Prior to conclusion of the study, a facilitated focus group comprised of two groups (urban or rural) will be assembled to present the qualitative themes gained from the semi-structured interview. Subjects selected for the focus group will be representative of the state's population by age, gender, socio-economic, geography, and ethnicity. Some individuals may represent more than one characteristic.

11.Data Analysis

Qualitative Analysis: Data for qualitative analysis will come from the semi-structured interviews. Each interview will be anonymized using an identification number. The key between subject and identification number will be held on a secure encryption device held in a secure location of the primary investigator's office. The interview will be transcribed verbatim using a transcription application from Olympus. Investigators will examine the transcripts to ensure accuracy, resolve misspellings, or resolve missing sections due to poor sound reproduction. The transcriptions will be sent to the participant via U.S. post, facsimile, or email in order to check for accuracy (member checking). Transcripts will be analyzed using resources from the CTSC utilizing qualitative analysis software to help with organizing, sorting, and arranging the

materials for analysis. Codes will be generated via the software and used to assist investigators in developing thematic material. Team members will confer and reach consensus on the results (peer debriefing). Iteratively, the meaning of the content will be derived and prepared for reporting. The de-identified transcripts and data will be subjected to auditing by an outside auditor with expertise in qualitative research methods. All media: paper and electronic will be held in secure offices within locked metal filing cabinets. Electronic media will have further security using devices meeting federal standards for encryption and password protection.

Quantitative analysis will be analyzed by Dr. Dionne with assistance from a graduate student employee using SPSS.

12.Provisions to Monitor the Data to Ensure the Safety of Subjects

The study is not expected to involve more than minimal risk to participants. Some people may experience sadness depending on the effect of COVID on their lives and changes or losses encountered.

13.Withdrawal of Subjects

Participants will be free to withdraw from the study at any point. However, any previously collected data will remain for use in the study up to the point of termination from the study. Withdrawal should be in writing, although it may be anticipated that some participants may terminate orally. Investigators will respect the autonomy of participants and record the oral termination. Reasons for participants to terminate from the study could include several precipitating events: change in residence, change in health status, inconvenience, timing, or other subjective or objective factors. Reasons for investigators terminating participants from the study might include abusive behavior of participants, unable to contact the participant for follow-up, or potential cognitive change of participant that might impair ability to consent. The ability and conditions of withdrawal will be stated clearly in the consent document.

14.Data Management/Confidentiality

The members of the research team having access to the data include the investigators (PI, Co-PIs, graduate student investigators added to the project who have completed HIPAA and CITI training). Once all data collection is completed, the only team member requiring access to the identifiable data will be the PI and Co-PIs. The research will not require disclosing any protected information. The research team does not anticipate receiving any information that requires additional protections (i.e. HIV status, etc.). Because the research is being conducted using NIH funding and is registered in clinicaltrials.gov, a Certificate of Confidentiality will be used to protect the data from forced release. Although the risk of exposure of identifiable information is remote, a participants identify might be deduced depending on the nature of disclosures they make during the interview and the geographic region they reside.

Extreme care will be taken to protect the data using UNM HSC IT recommended technology for encryption and password protection. The team will purchase a portable storage device (jump drive) for that purpose. Only the PI and Co-PIs will have physical control of storage devices. Identifiers will be held separately from the storage device, in the PIs secure office, in a secure and locked metal filing cabinet. Each participant will be given a unique code for data analysis purposes. In every instance, identifiable information is secured separately from the data and participant code. Identifying data will be held for three years, per IRB recommendation, and thereafter destroyed using a secure shredding bin. The identifying data includes the audio recordings of participants. De-identified data will be kept indefinitely for manuscript purposes. Data will not be transferred electronically and work with the data will occur on non-networked computers owned by the division. No identifiable health information is being collected.

15.Data and Specimen Banking

N/A

16.Risks to Subjects

The investigators anticipate minimal risk to subjects being surveyed and interviewed for the study. However, due to the severity and extent of the COVID-19 health emergency, they do anticipate some participants may express extreme stress, depression, or anxiety. The investigators will have a readily available and sharable list of mental health resources, financial resources, and food bank resources to mitigate distress caused by the emergency. Reversibility of risks depends on the length of the health emergency and improvement in socio-economic status for some participants. These may be outside the direct influence of investigators, but efforts to mitigate will be offered through providing reliable information and referral. Through careful handling of data, as described above, investigators will minimize the risk of breach of confidentiality and/or privacy. The risks will be described in the consent.

Since participants will be giving individual interviews, it is not likely the procedures will put non-participants at risk. However, if participants disclose being victims of domestic violence or perpetrating domestic violence or performing acts of abuse or neglect of children or elderly co-habitants, it is necessary in the consent to give warning that as health professionals, the investigators would be bound to report such disclosures per state law.

17.Potential Benefits to Subjects

No direct benefits are expected to accrue to research participants.

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18.Recruitment Methods Where I left off:

All recruitment material(s) (e.g., advertisement, flyer, e-mail, letter, phone script, etc.) to be used in the study must be submitted with this exemption request.

This is a prospective study. Research will be conducted via telephonic or wireless technologies enabling individual contact with prospective participants. Researchers will be based in HSC offices or, from work at home locations as determined by the HSC as necessary due to the pandemic. Prospective participants will be reached via public directories available across every New Mexico county and a random pattern will be used to systematically use the directory listings. There will also be opportunities for participants to elect to contact the researchers in order to be surveyed, by placing print notifications via public service announcements to rural and urban news organizations or via advertisement. Respondents will also have the option of writing their responses and returning by mail.

19.Provisions to Protect the Privacy Interests of Subjects

Data will be collected, maintained, and archived or destroyed per HSC Data Security Best Practices, including:

1. **Best Practice for data collection** is for it to be directly entered onto a data collection form that is in a secured access folder on an HS drive behind a firewall, or in a secure UNM Data Security approved system such as RedCap.
2. **Data collection of de-identified data**, if done in a clinical setting or other setting that does not allow direct entry into a secured system, may be done temporarily using a personal or university owned electronic storage device or hard copy document. **The important security safeguard is that no identifiers be included if the data is entered or stored using an untrusted device or storage.**
3. **Permanent (during data analysis, after study closure**) storage must reside on HSC central IT managed storage. Processing of data (aggregation, etc.) are to be carried out in such a way as to avoid creating/retaining files on untrusted storage devices/computers. Trusted devices are HSC managed and provide one or more of following safeguards: access logs, encryption keys, backups, business continuity and disaster recovery capabilities.
4. **Alternate storage media** must be approved by HSC IT Security as meeting or exceeding HSC central IT provided security safeguards.

Our process is to immediately de-identify data collected so that privacy is maintained.

20.Economic Burden to Subjects

N/A

21.Compensation

NONE

22.Consent Process

23.Documentation of Consent

There will be an IRB approved consent process. Participants **MUST** be provided study information to include a disclosure that the activities involve research, a description of the research procedures, a disclosure that participation is voluntary and the name and contact of information of the PI. This can be in the form of a letter, email, verbal script or information sheet. Consenting will take place with members of the approved research team: Dr. Wilhite, Poole, and Dionne, and graduate student researcher Grit Ramuschat.

24.Study Test Results/Incidental Findings

Study results will be aggregated data and thematic data.

25.Sharing Study Progress or Results with Subjects

The researchers intend to share the findings by submitting to journals. Participants can elect to opt in to receive research results.

26.Inclusion of Vulnerable Populations

Screening for eligibility will occur at time of making contact. Pregnant women are not excluded from participation because this special status is not relevant, the research poses less than minimal risk, and pregnancy is not the focus of the study. Exclusion: Incarcerated individuals, children, and those with inability to give consent will be excluded from the study.

27.Community-Based Participatory Research

N/A

28.Research Involving American Indian/Native Populations

Native American/American Indian subjects are not the key focus of this research, and recruitment will not occur on any tribal nations, but American Indian/Native Population individuals may elect to participate in the research.

29.Principal Investigator's Assurance

By submitting this study in the Click IRB system, the principal investigator of this study confirms that:

☒ The information supplied in this form and attachments are complete and correct.

☒ The PI has read the Investigator's Manual and will conduct this research in accordance with these requirements.

☒ Data will be collected, maintained and archived or destroyed per HSC Data Security Best Practices, including: