NORTHERN ARIZONA UNIVERSITY

Office of Research Compliance

CARDIOCARE QUEST: A CO-CREATED GAME FOR IMPROVING HYPERTENSION TREATMENT COMPLIANCE IN ARIZONA

April 14*, 2024*

NAU NORTHERN ARIZONA UNIVERSITY

Office of Research Compliance

Consent to Participate in Research

Study Title: CardioCare Quest: A Co-created Serious Game for High Blood Pressure Healthcare Compliance
Principal Investigator: Jared Duval, PhD; Tochukwu Ikwunne, PhD; Creaque Charles Tyler (Texas State University), PharmD

Summary of the research

This is a consent form for participation in a research study. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

You are being asked to participate in a study about creating a serious game for health (called CardioCare Quest) that enhances treatment compliance of High Blood Pressure (HBP) for indigenous populations. CardioCare Quest will offer an enjoyable way for individuals to stay connected to their HBP treatment plans while providing valuable data for medical professionals. As a participant in this study, you may be requested to help us develop new features and improve or evaluate CardioCare Quest. The information we need includes your ideas for developing and improving CardioCare Quest, as well as your evaluation of CardioCare Quest. CardioCare Quest's development may necessitate you completing a survey/interview for research purposes. Direct potential benefits to subjects include free access to a tool that may benefit their HBP treatment therapy and shape future improvements to CardioCare Quest that will make your experience better. All research activities pose minimal risk.

Why is this study being done?

This is a research study, and the purpose of the study is to create a serious game for health that can enhance high blood pressure patients' adherence to treatment plans and improve their knowledge about their condition.

What will happen if I take part in this study?

You will be interviewed about your HBP treatment therapy experiences. All interactions with participants will be conducted in a safe setting. We will either meet in our research lab locations on campus, virtually via video conferencing software (Zoom), or at locations convenient to participants such as their offices. Interviews may be conducted with individual participants or as part of a focus group. You can opt-in to receive surveys about how existing games or interventions have integrated real-world exercise and gamification elements for HBP patients. Participants will be asked to create low-fidelity prototypes of potential new CardioCare Quest

features, content, and artifacts using low-cost materials such as paper, drawing utensils, popsicle sticks, stickers, and tape or will use Adobe XD or Figma to create medium-fidelity digital prototypes. You will also be involved in brainstorming and bodystorming sessions to ideate many possible solutions for Cardiocare Quest for enhancing high blood pressure education and patients' adherence to treatment plans.

How long will I be in the study?

All surveys should reasonably take less than 1 hour. The maximum time commitment for the interviews and focus group discussion within the bodystorming and brainstorming sessions will take between 30 minutes to an hour for each interview or focus group discussion. Ethnography will be used to observe HBP treatment therapy practices at home, in clinics, and in pharmaceutical shops within 30 minutes.

How many people will take part in this study?

The number of participants will not exceed 100 collectively due to resource restraints. We will recruit appropriate stakeholders that are appropriate for each session's unique goals.

Can I stop being in the study?

Participation is completely voluntary, done at your leisure, and dependent on participants' interest. We do not foresee needing to withdraw any subjects because the research poses minimal risk. Participants will be encouraged to stop participating if they are uncomfortable at any time. In the unlikely event that someone is injured during research activities, we will call the appropriate authorities and the study team will contact the IRB, the compliance hotline, or appropriate officials to address the issue.

What risks or benefits can I expect from being in the study?

All research activities pose minimal risk. As unlikely as it is, the risk of accidental disclosure of information relating to technology familiarity, treatment tasks, user experience information, and design artifacts is possible. This could potentially cause emotional distress and be embarrassing or stigmatizing if revealed. Another risk is the potential for a breach of privacy or confidentiality. All information gathered from the sessions will be encoded and interpretable only by trained individuals involved with the research. None of the information gathered will impact participant eligibility for services, insurance, or employment if accidentally disclosed. In the case of a breach of participant privacy or confidentiality, participant injury, or any other unanticipated problem, the study team will contact the IRB, the compliance hotline, or appropriate officials to address the issue. For ethnographic observation in clinical settings, pharmaceutical shop settings, and hospital settings, accidental exposure to information relating to technology familiarity and HBP treatment therapy practices could cause emotional distress or be stigmatizing if revealed. For this reason, ethnographic observations will not be recorded

only observations will be made in locations where they normally do HBP treatment therapy during their normally scheduled HBP treatment therapy sessions. At the beginning of observed sessions, Cardiologists will introduce the researcher and the researcher will assure the HBP patients that we are just there to watch, not grade, and that we hope they have fun. If the researcher's presence is causing the patient to be anxious or disrupting the potential benefits of the HBP treatment therapy session, the researcher will leave.

Will I be paid for participating in the study or experience any costs?
Participants who participate in this study will be entered to win a $100 Amazon gift card. There is a 1/10 chance of winning and 1 gift card will be purchased for every 10 individuals who participate. Anyone who asks will be entered into the drawing. Participants will stay entered in the drawing even if they withdraw. The consent forms make it clear that the drawing is not contingent on participation in the study.

Will my study-related information be kept confidential?
The participant's name will not be used in any report. Identifiable research data will be encrypted and password-protected. While researchers follow procedures to maintain your confidentiality, as with any internet activity, we cannot guarantee confidentiality of interception of data sent via the Internet by any third parties.

The information that you provide in the study in the form of a survey, interviews, and focus group discussions will be handled confidentially. In addition, by observing HBP treatment therapy in different contexts, we will gain insights into game features that may help CardioCare Quest perform in various contexts. By observing people use CardioCare Quest in various contexts, we can understand where it works well, how people appropriate it in novel ways, and where it breaks down so that we can improve the game for the various contexts it is used. Before conducting ethnographic observations, we will collect a letter of permission from the clinic, hospital, or pharmaceutical shops. The subject identifiers we will collect for Ethnography include participant names, phone numbers, and email addresses. In addition to collecting these subject identifiers, we will save our ethnographic notes for later analysis. Healthcare providers typically obtain HIPAA Authorization from patients as part of the initial intake process or during subsequent interactions where the disclosure of protected health information (PHI) is necessary for treatment, payment, or healthcare operations. This authorization allows healthcare staff to discuss the patient's medical information within the boundaries specified by HIPAA without violating the patient's privacy rights.

However, there may be circumstances where this information must be released or shared as required by law. Northern Arizona University Institutional Review Board may review the research records for monitoring purposes.

The information that participants provide in the study will be handled confidentially. However, there may be circumstances where this information must be released or shared as required by law. The Northern Arizona University Institutional Review Board; other federal, state, or international regulatory agencies; or the study's sponsor, if any, may review the research records for monitoring purposes.

National Institutes of Health (NIH) Certificate of Confidentiality: To help us protect your privacy, we have a Certificate of Confidentiality (CoC). This certificate protects you by preventing researchers from sharing your identity with any Federal or State representatives should information about you be requested (for example, if law enforcement requests information in a criminal investigation). Please note that researchers are not prevented from the voluntary disclosure to report issues such as child abuse or report to prevent a threat to the safety of self or others. Your study information will be treated as confidential, as permitted by both Tribal and US Federal law. This certificate does not supersede Tribal Law and when on Tribal Land, Tribal law will govern.

Will my study-related information be used for future research?

Information that may identify you may be used for future research or shared with another researcher for future research studies without additional consent. Any data shared with other researchers or to the public domain must be de-identified or anonymized to prevent the disclosure of personal information.

Who can answer my questions about the study?

For questions, concerns, or complaints about the study, you may contact Dr. Jared Duval by emailing him at Jared.Duval@nau.edu or by calling him at 928-523-0429 or Dr Tochukwu Ikwunne by emailing him at Tochukwu.ikwunne@nau.edu or by calling him at 928-266- 8389.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Research Protection Program at 928-523-9551 or online at http://nau.edu/Research/Compliance/Human-Research/Welcome/.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Jared Duval. In the case of any injury, the study team will contact the IRB, the compliance hotline, or appropriate officials to address the issue.

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AGREEMENT TO PARTICIPATE

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I affirm that I am at least 18 years of age and voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject	Signature of subject	Date

AGREEMENT TO BE AUDIORECORDED

Subject Signature:_____ Date:_____

AGREEMENT TO BE VIDEORECORDED

Subject Signature:_____ Date:_____