Title: Examining the Individual Response to a Restricted Sodium Diet in Hypertensive Patients

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Consent to be part of a Research Study
To be conducted at
University of Texas Health Science Center at San Antonio

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.
Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety, and welfare as a participant in the research. The PI for this study is Jisook Ko, Ph.D., RN, and Assistant Professor of School of Nursing University of Texas Health Science Center at San Antonio.

Funding
National Center for Advancing Translational Sciences, National Institutes of Health, Grant KL2, is funding this study. This organization is providing money to the UTHSCSA School of Nursing so that the researchers can conduct the study.

Purpose of this study – "Why is this study being done?"

You are asked to participate in this research study of the restricted sodium diet for pre-hypertensive patients. The purpose of this study is to examine the individual responses to a restricted sodium diet and explore the association of salt sensitivity with dietary sodium intake and blood pressure control compared with standard care for pre-hypertension.

The researchers hope to learn underlying mechanisms of individual differences responded to a restricted sodium diet and how the sodium restricted diet alters metabolic responses and improve blood pressure control.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are an adult and have been diagnosed with pre-hypertension.

How many people are expected to take part in this study? This study will enroll approximately 40 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend approximately 2 visits with the researchers or study staff. It may be necessary for you to return to the study site (School of Nursing) at baseline (start of intervention and 8-weeks (end of intervention).

The first visit including information session regarding intervention, using wireless, wearable, and mobile app, and 24-hour urine collection will take approximately 60 minutes and the following visit will take about 30 minutes.

Study includes more than one group.

Assignment to Study Groups
When it is determined that you are eligible for the study, you will be assigned by chance like flipping a coin to one of two groups. You will have an equal chance of being assigned to either group, and you will be told which group you are assigned to.

- Group 1: Intervention group – this group will receive the Sodium-Watcher Program which is a hypertension intervention consisting of 8 weeks of education sessions regards to a specific sodium restrictive diet (45 minutes). In addition, this group will receive a Fitbit wristband and a wireless blood pressure monitor to track daily diet and blood pressure.
- Group 2: Control group – this group will continue to receive their routine care for hypertension that consists of a recommendation to follow sodium-restricted diet and take medications as prescribed. In addition, this group will receive a Fitbit wristband and a wireless blood pressure monitor to track daily diet and blood pressure.

Study Procedures - as a participant, you will undergo the following procedures:
Baseline / Start of intervention visit at the School of Nursing

- You will have a blood draw (about 1 tablespoon) for salt sensitivity genes.
- You will measure your height and weight.
- Collect demographic information.
- The research team will provide you with information and instructions on using the Fitbit mobile app, Fitbit wristband and in-home blood pressure monitor while at home.
- Group 1: You will be given tutorial of sodium-restricted diet intervention.
- You will receive a self-collection urine kit and a voided urine sample will be obtained at the day after baseline visit. The research staff will visit your home and pick up the 24-hour urine collection at your convenient time.

Over the next 8-weeks at your home

- You will measure your daily blood pressure using the digital in-home blood pressure monitor.
- If you are assigned to Group 1, you will receive weekly instruction and education (45 minutes) through Zoom video calls and online instruction delivered to phone or computer. And, you are asked to adhere to the specific Sodium Restrictive Diet that will be developed specifically for you as part of the study. Additionally, you will continue to follow the recommendations of your physicians for managing your hypertension risks.
- If you are assigned to Group 2 you should continue to follow the recommendations of your physician for managing your hypertension risks while also participating in the self-monitoring activities for the research study.
- You will self-monitor your diet using the Fitbit mobile app and Fitbit wristband.
    - The data collected from these devices will be automatically shared with the research team - a member of the research team will contact you if your information is not routinely updated within the platform to ensure that you are completing the study procedures.

End of intervention visit (8-week) at the School of Nursing

- You will measure your height and weight.
- You will receive a self-collection urine kit and a voided urine sample will be obtained at the day of 8-week or a day after 8-week visit. The research staff will visit your home and pick up the 24-hour urine collection at your convenient time.

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

Future Use of Your Information or Biospecimens Collected as Part of Your Participation

Identifiers may be removed and the de-identified information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Return of Research Test Results for Genetic Tests to Subjects

It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. There are no plans to provide this information to you or your physician.

Risks – "What are the risks of participation in the research?"

Risks from the research

Participation in this study may involve some added risks or discomforts.

Risks associated with the Sodium Restrictive Diet (Group 1) include those which are:

These potential risks have been seen in observational studies and were experienced in extreme sodium reduction.

Rare and Serious (Less than 1 out of 100)

- Increased risk of death in patients with heart disease (heart attacks, strokes)
- Increased risk of death in patients with heart failure and diabetes
- Increased risk of LDL and triglycerides

Risks for blood sampling may include those which are:

Likely and Not Serious (20-30 subjects out of 100),

- Bruising at the site of the blood draw

Less Likely and Not Serious (5-10 subjects out of 100)

- Feeling faint, dizzy, or lightheaded.
- Infection may occur.

Use of Fitbit and BP monitor:

Breach of confidentiality- It is possible in a rare occurrence there may be a breach of confidentiality. However, the researchers have taken steps to minimize this risk by keeping research data stored securely and reporting data without the use of information that could identify you as taking part in this study. Any list connecting real names and identifiers with codes will be stored in a separate location from the study data. This list will be destroyed when the study is finished.

Genetic Informational risks related to the study

This study will include genetic testing. Human tissue contains genes that determine many of a person's physical characteristics, such as the color of eyes and hair. In some cases, genetic testing of tissues can be used to indicate a risk for the development of certain diseases. Genetic information is unique to each individual and could potentially be used to discover possible changes in a person's future health status or life expectancy, or that of his/her children and family members. Even if your tissues are used for this type of research, the results will not be put in your health records. Releasing this information to you could cause psychological distress, anxiety or family problems.

Releasing this information to others, such as including it in your medical record, may pose a possible risk of discrimination, or increase difficulty in obtaining or maintaining disability, long-term care, or life insurance. These risks would occur if your information is released by mistake. The measures being taken to protect your privacy are discussed below and make this possibility unlikely.

Even though the results of genetic testing may not be linked to you, it is possible that people of your ethnic background may be found to be at more risk for certain diseases based on future genetic research and this information might harm you in the future as a member of the group. Also, there may be unknown risks of genetic testing in the future.

Are there Risks related to withdrawing from the study?
If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.
If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.
If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"
The possible benefit of your participation in this study is learning about the sodium-restricted diet, which may help improve your hypertension self-management. There is no guarantee or promise that you will receive any benefit from this study. We hope the information learned from this study will benefit other people with similar conditions in the future.

Payments – Will there be any payments for participation?
As payment for your time and attention to the elements of the study protocol, you will receive $60 at the end of the 8 week study period.

Costs – Will taking part in this study cost anything?
The sponsor will provide the study devices (Fitbit and blood pressure monitor) free of charge during this study. At the end of your participation you must return all unused study device to the researcher.

There is no direct cost to you for taking part in this study. However, data rates may apply when using the activity and diet tracker app on your smartphone, depending on your cell phone and data use plan.

Confidentiality – How will your records be kept confidential?
Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include: information that is created or collected during your participation in the study including medical and treatment history, information you give us during your participation in the study such as during interviews or from questionnaires, results of blood tests; and demographic information like your age.
We will get this information by asking you.

How will your PHI be shared?
Because this is a research study, we will be unable keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- the members of the local research team
- The Institutional Review Board and the Compliance Office of the University of Texas Health Science Center at San Antonio, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Health Science Center at San Antonio.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.
Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to **Jisook Ko, 7703 Floyd Curl Dr. Mail Code 7975, San Antonio, TX 78229**. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study. You will only have access to your PHI until the study is complete.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

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Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Jisook Ko, PhD, RN can be reached at 210-567-5554.

The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.

Adult Signature Section

- You have voluntarily decided to take part in this research study.
- You authorize the collection, use and sharing of your protected health information as described in this form.

Printed Name of Subject	Signature of Subject	Date	Time AM PM
Printed Name of Witness	Signature of Witness	Date	Time AM PM

☐ *Check if consent and authorization obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English. Have witness initial below.*

Declaration of witness: I was present for the entire consent process. _____ ←(initials of witness)

Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent and Authorization	Date	Time AM PM

☐ Consent and authorization was obtained from this individual who is unable to read and/or write but can otherwise communicate and/or comprehend English. The method used for communication with the subject was: _____.
The specific means by which the subject communicated agreement to participate was:
_____