BRAIN SAFE: Consumer Intervention to reduce exposure to drugs linked to Alzheimer's Disease

NCT04121858

Version Date: April 1, 2021

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

BRAIN SAFE
#1811254189
Sponsored by the US National Institutes of Health (NIH)

ABOUT THIS RESEARCH
You are being invited to participate in a research study that may assist you with tracking your medications and communicating about what you are taking with your physicians. Many medications have known side effects and having a current list of medications to review with your physician may assist your provider in giving you better care. This project is a paid study and is supported by the National Institutes of Health. The answers gained in this important research project may provide information that might help change or improve current treatment methods in the future.
You were selected as a possible subject because you are at least 60 years old and taking medications. This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY
You may choose not to take part in the study. You may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Eskenazi Health or IU Health.

WHY IS THIS STUDY BEING DONE?
The study purpose is to reduce older adults' exposure to harmful medications and improve brain health. By participating in the study your involvement helps us provide information on health concerns that you can discuss with your physician.

The study is being conducted by the principal investigator Dr. Richard Holden, PhD, of the Indiana University School of Medicine, Indianapolis. The study is sponsored by the US National Institutes of Health (NIH) and the IU School of Medicine Center for Aging. To contact Dr. Holden and his staff call: 317-260-6280, or email him at bsafe@iu.edu.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
If you agree to participate, you will be one of 700 individuals participating in this research.

WHAT WILL HAPPEN DURING THE STUDY?
This study involves collection of information about you or from you. If you agree to be in the study, you will do the following:

At the beginning of the study, and then 6 months later and 12 months later, you will be asked to complete thinking and memory activities and questionnaires about you and your health. Each of the three appointments may take up to two hours, but can be split up into multiple sessions if requested. Study staff will meet you at your home or you can come to our office or to Eskenazi or IU Health. Transportation can be provided for you at no cost. If transportation is not possible a phone-based appointment can also be completed.

You will also be randomized into one of two groups. Randomization is like choosing your group by flipping a coin; you cannot choose your group. Based on your assigned group, you will receive a program or "app" that will either ask you to log the medications you are taking, or will inform you about medication safety. The app you are assigned will be loaded on your personal smartphone. If you choose not to use your smartphone or if you do not own a smart phone, we will loan you a device, free of charge. We will ask you to use the app at least once a month, and will remind you to do so. We will measure how you use the app. At the end of the 12 months of study, we will contact you to schedule a final appointment. At that appointment we will collect the loaned devices or request to delete the app from your personal phone. If you wish to continue to use the app after the conclusion of your participation in the study, we will continue to have access to and will potentially collect data from the app.

Study personnel will ask for permission to look at your medical records to collect information about your medical history, medications, treatments, and examinations during the study period. You will be asked to fill out and sign a separate permission form.

WHAT ARE THE RISKS OF TAKING PART AND HOW WILL MY INFORMATION BE PROTECTED?

Since this study only includes collection of information about you, the only risk to you is a possible loss of confidentiality. We will do everything possible to protect your information. This includes keeping your information in protected electronic databases that can only be accessed by research staff. Your information will be used for research only. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study and databases in which results may be stored.

The app is protected so only you can log in. Data in the app are stored securely. Information about how you use the app will be linked to your subject ID but not to your name. We do not collect research data on what else you do on your phone. However, if a phone was provided by the study, we may be notified if the phone is being used for inappropriate or illegal activities.

There is a minimal risk that educational/informational content in the Brain Safe Intervention app will cause you to change your thoughts and behaviors regarding your medications. This may cause you to change behaviors prior to speaking to your physician. It's important to discuss all concerns with your physician prior to making any changes to your prescribed medication.

It is possible that some of the study questions could make you uncomfortable or tire you. The research staff who will be asking questions are trained to recognize and minimize this discomfort.
You may skip any questions you do not want to answer. You may stop the tests at any point or ask the researcher to contact you later.

HOW WILL MY INFORMATION BE PROTECTED?

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, the study sponsor (The National Institute on Aging of the NIH) and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the NIH, who may need to access your medical or research records.

A description of this clinical trial will be available on **ClinicalTrials.gov**, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?
You may learn information that is helpful to you. We do not expect you to receive other direct benefits from taking part in this study, but we hope to learn things that will help scientists in the future.

WILL MY INFORMATION BE USED FOR RESEARCH FOR FUTURE USE?
Information collected from you or about you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR PARTICIPATATION?
You will receive payment for taking part in this study in the form of gift cards and small non-monetary token items. You will receive a $25 gift card each time you complete an appointment, at the start of the study, at 6 months, and at 12 months. This trial uses an App and requires a mobile phone. If you do not own a suitable mobile phone, the study will provide you with a phone for a year free of charge.

WILL IT COST ME ANYTHING TO PARTICIPATE?
There is no cost to you for taking part in this study.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?
For questions about the study, contact the researcher team at (317) 260-6280 or leave a voicemail. For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the Indiana University Human Subjects Office at 800-696-2949 or at irb@iu.edu.

For medical help, please contact a medical professional. In the event of an emergency, please seek appropriate medical treatment, such as calling your primary care physician, visiting an emergency department, or calling 911.

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future care. If you decide to withdraw, please contact the study staff at (317) 260-6280.

Your participation may be terminated by the investigator without regard to your consent in the event that you decline to conduct study activities, fail to communicate with or mistreat study staff. This study may also be terminated by the NIH, investigator, or Data Safety Monitoring Board if the intervention may put you at higher risk than expected. You will be told about new information about the study that may affect your health, welfare, or willingness to stay in the study.

PARTICIPANT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's Printed Name:_____

Participant's Signature:_____**Date**:_____

COMPLETED BY RESEARCHER

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date**:_____