

INFORMED CONSENT

Title: mHealth technology driven assessment of energy drink consumption and health outcomes. (mTECH)

Protocol No.: #16-52

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SUMMARY

You are invited to participate in a research study to understand the effects of energy drink use on different health outcomes, such as physician/ER visits, medication use, blood pressure, heart rate, activity level, and sleep. The study is designed for United States residents above the age of 18 years old with an Apple device with iOS 8.0 or higher.

Your participation is entirely voluntary and your decision whether or not to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you are free to stop your participation at any time without penalty or loss of benefits to which you are otherwise entitled.

If you have any questions about your rights as a participant in a research project please call the Research & Graduate Studies Office, University of the Pacific (209) 946-3903. In the event of a research-related injury, please contact your regular medical provider and bill through your normal insurance carrier, then contact the Office of Research & Graduate Studies.

PURPOSE OF THIS STUDY

As smartphones and wearables gain more sensors, abilities, and popularity, mobile health (mHealth) will become a more important part of data collection for clinical trials and healthcare. Also, energy drink use is on the rise, but there is little understanding about the long term effect of energy drink use. Our study will look at both of these issues by using mHealth technology. By the end of our study, we hope to describe the effects of energy drinks and their impact of different health markers, such as blood pressure, heart rate and sleep.

How long will I be in the research study?

Your participation in this study will last for a total of 31 days, which is made up of a survey of up to 19 questions (estimated: 15 minutes) and one daily question for the next 30 days (estimated: 1 minute per day).

PROCEDURES

What will you be asked to do?

If you decide to join the study, you will be required to download the free study application on your Apple device with iOS 8.0 or higher from the United States Apple App Store. You will

need to confirm your eligibility and accept the informed consent prior to enrolling in the study. Also, the study will ask your permission to access certain health data from the Health App. Periodically, we will ask you to answer survey questions. The data sent to the study will include your responses to the survey questions and your health data gathered from your phone itself.

It is important to note that this study is making NO recommendations in regards to changing your behavior, such as the type or how many energy drinks to consume.

- **Surveys:** After starting the study, you will be asked to complete a survey, which includes up to 19 questions. These questions are designed in order to help the study better understand your overall health, caffeine intake, energy drink usage, and the potential effects of energy drinks. Daily, you will be asked to complete a one question survey about the previous days energy drink usage. All survey questions are mandatory and may not be skipped in order to move on to the next step.
- **Health Data:** This study will also ask for permission to access certain health data stored in your Health app on your iPhone. The app will ask for systolic blood pressure, diastolic blood pressure, heart rate, distance exercised, daily step count, and sleep activity. This is data that you may have entered in manually previously or is synced to your iPhone via a connected device (e.g. Apple Watch, Jawbone, Fitbit, and more). The amount of health data collected will be limited to the 30 days before you joined the study and for the 30 days after starting the study. You will have the ability to specify which health data you would like to share with the study. At any time point during your participation in this study, you have the ability to revoke access from the study to collect any additional specific, or all, of your health data.

All data collected, from surveys and health data, will be collected to ensure that your privacy will be respected and will not be traceable back to you.

What will we do with your data?

After completing the study analyses, de-identified summary data may be presented as a poster or a full manuscript at a scientific meeting or journal respectively. This is done so that others may benefit from the study results.

RISKS AND BENEFITS

What are the possible risks from being in this study?

There are possible risks associated with any research study. This study does not involve testing any new drugs or therapies, so we do not expect any medical side effects from participating in this study.

The primary concern associated with this study is privacy risk. It is important to note, that any data collected from your device is stripped of all identifiers, which means that in the rare chance that an unauthorized personnel accesses the collected data, they will not be able to traced back to you. There is the risk that others may see the app or app notifications appear on your device,

however, they will not be able to find any private information from seeing the app installed on your device. If someone finds your phone, they will not have access to your health information or energy drinks statistics by opening up the mTECH study app. In this scenario, minimal loss in confidentiality may occur as the finder of your phone may be able to determine that you are taking part in the study, but they will not be able to find any of your submitted information from opening the mTECH study app. Note that you may be storing health data in the Health App on your iPhone, however mTECH does not have the ability to protect this information because it is an app controlled by Apple and not this study's investigators. If you are concerned about your confidentiality, you have the ability to add a "passcode" to your device in order to protect against unauthorized users from unlocking your device. Deleting the study app from your device will remove all study information from your device, removing all evidence of your participation in the study.

There is the possibility that you may feel the need to change some of your behaviors, such as your energy drink use, because you know that you are in a study. It is very important to remember that this study is NOT asking you to change any of your behavior. Any need to change any behaviors should be done through your own decisions after careful thought.

The overall adverse effects of energy drink use are not well understood, but there have been some reported incidents of emergency room visits or even death. This is not a risk brought on by participation in this study, but it is important that you are aware of these reports and that this study is not currently making any statements on energy drink use.

This study does not ask that subjects take part in any illegal activities. For example, it is important that you do not operate your mobile device while driving and only conduct study activities in a safe environment.

Are there any costs associated with being enrolled in this study?

The study app mTECH is free. There is no direct cost to joining this study.

The main cost is time, which is about 30 minutes on the first day and then about 1 minute per day for the next 30 days.

The study app may take up to about 100 megabytes of storage on your smartphone. It is important to note that this study will be transferring data from your device to the study server, which may cause you to have or increase your cellular data usage costs. This cost is to be paid for by the participant and at no point will the investigators or the University of the Pacific be liable for these charges. It is recommended that you connect to a free WiFi service to avoid these costs.

All costs directly or indirectly related to the study will be the responsibility of the participant.

What are the possible benefits from being in this study?

There have been many studies done on the effects of energy drinks on blood pressure and heart rate in the acute setting. However, we will build upon previous studies by looking at the long

term effects of chronic energy drink use and its impact on health. Also, there is a push in the scientific community to use patient owned devices, such as smartphones and wearables, in clinical trials, however, there are currently no accepted models or best practices published on these techniques. By completing this study, we hope to create generalizable knowledge and a model on how to better structure future studies. Results from our study may also help public policy decision making with regards to the health impacts of energy drinks.

However, any benefits that are derived from the work of this study may not be of direct benefit to you, therefore we cannot, and do not, guarantee or promise that you will personally receive any direct benefits from this study. There are no direct financial or utilitarian benefits for participating in this study. Indirect benefits for some subjects may include a change in behavior to increase their overall health as a result of being aware of their energy drink usage and overall health. Subjects may also gain satisfaction in knowing that they have contributed to a research study.

How do I end my participation in this study?

You may stop participating in this study at any time without any penalties or loss. In order to withdraw from the study, you only need to delete the study app from your smartphone. Deleting the app from your device will remove all links between you and the study. If you are withdrawn from the study, since the investigators will not be able to identify that data to you, the collected data will not be removed from the research study database and will continue to be used to complete the research analysis.

The study investigators may also withdraw you from the study without your consent at any time for any reasons, including if it is in your or the study's best interest or if the study is ended/cancelled.

CONFIDENTIALITY

Any information that is obtained in connection with this study will not contain any identifiers. Subjects may be able to view their own recorded information on their own device. However, only investigators will have access to the collected participant data. All data, although de-identified, will still be stored in a password protected manner.

After completion of the study, data may be presented as a poster or full manuscript at a scientific meeting or journal respectively. Upon completion of the study enrollment period (6 months), the data will be available for analysis for a period of 2.5 years. After 6 months, the study app will no longer be available for download. You may choose to keep the app on your Apple device after it is no longer available on the Apple App Store. The app will be inactive, other than providing you with your own submitted information, once the study is complete or you have completed your portion of the study. If the app is ever deleted or reinstalled, all data will be destroyed from the participant's device.

All reports and publications will only provide aggregate data without specific identifiers.

Informed Consent and Authorization

By agreeing to this survey, you indicate that you have read and understand the information provided to you, that you willingly agree to participate, that you may withdraw your consent at any time and discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled and that you are not waiving any legal claims, rights or remedies.