Distracted Driving App Study for Teens and Parents/Caregivers

NCT04177524

Informed Consent Form - 02/25/2020

Children's Hospital of Philadelphia

Informed Consent and HIPAA Authorization Form

Study Title: An informatics approach to preventing distracted driving

Version Date: February 25, 2020

Consent Name: IDD Informed Consent

Principal Investigator:	Allison E. Curry, PhD, MPH	Telephone: 267-425-1525
Study Coordinator:	Lauren O'Malley, MPH	Telephone: 267-425-0382

You, or your child, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

In the sections that follow, the word "we" means the principal investigator and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to you as the parent and "your child" refers to your child.

Study Overview

You and your child are being asked to take part in this research study because you and your child are licensed drivers.

The purpose of this research study is to figure out if a new cell phone app helps to decrease distracted driving, and learn about parent and teen perspectives about the app.

You and your child will be asked to participate in a 12 week study about cell phone use while driving. If you take part, you and your child will be asked to use an app on your phone that tracks your cell phone usage while in a moving vehicle. You will also be asked questions about yourself, your cell phone usage, and your experience with the app. We will separately ask your child to answer questions about themselves, their cell phone usage, and their experiences with the app.

This is a minimal risk study and there are no known risks or discomforts beyond what you would encounter in day-to-day living.

You will not benefit directly from participating in this study.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

Participation in this study is voluntary. You are free to withdraw from the study at any time.

If you are interested in learning more about the study, please continue to read below.

How many people will take part?

About 200 parents and 200 teens will take part in this study.

What are the study procedures?

This study involves you and your child first taking an intake survey. Then, you will be invited to download an app to your cell phone and use this app over the next 8 weeks. You will be randomly assigned into 1 of 3 study groups. The only difference between the groups is the order in which you receive different features of the app. You will take part in 4 additional surveys throughout the 8 weeks of app usage and one additional survey at the conclusion of the study.

You may withdraw from the study at any time.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. The main risks of taking part in this study are discussed below.

Risk associated with Randomizatoin

You will be randomly assigned into 1 of 3 study groups. There is no difference in risk between any of the 3 study groups. There are no additional risks to driving with the app on your phone.

Risk associated with Questionnaires and Surveys

There are no physical risks but you or your child might experience momentary embarrassment or discomfort from survey questions. You do not have to answer any questions that make you too uncomfortable.

For any study involving the collection of data, there is the possibility of breach of confidentiality of data or loss of your privacy. Every precaution will be taken to secure your personal information to ensure your privacy and confidentiality.

Each participant will be assigned a study identification number. This number will be used on any data collection forms instead of your name and other private information.

Are there any benefits to taking part in this study?

There will be no direct benefit to you or your child from taking part in this study. The knowledge gained from this study may help in understanding how to prevent cell phone use while driving. This may benefit all drivers by decreasing motor vehicle crash rates, decreasing injuries and fatalities, and making roadways safer for everyone. Information collected from this study may benefit future generations of teen drivers and their families and may be used to improve teen driver policies aimed at keeping teens safe after they get their license.

Do you need to give your consent in order to participate?

If you and your child decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study. The study time commitments and responsibilities include a (30) minute intake phonecall, use of the app as directed, biweekly surveys lasting 10-15 minutes, and a post-study survey lasting 10-15 minutes.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You and your child do not have to take part in order to receive care at CHOP.

If you and your child decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled. Your child's current and future medical care at CHOP will not be affected by your decision.

Can you stop your participation in the study early?

You and your child can stop being in the study at any time. You do not have to give a reason.

What choices do you have other than this study?

The alternative to participating in this study is to not participate.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you and your child will be collected. This will include information from the study questionnaires. CHOP staff are required to keep your and your child's information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other researchers and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP, Minnesota HealthSolutions, and Life Apps, LLC (the app creators);
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.

- Groups monitoring the safety of this study;
- The Centers for Disease Control and Prevention who is sponsoring this research;
- Public health authorities that are required by law to receive information for the prevention or control of disease, injury, or disability (e.g., child abuse).

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Allison E. Curry, PhD MPH
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In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Financial Information

Will there be any costs to you?

There are no costs to you or your insurance for participating. The study sponsors are providing financial support and material for this study and the procedures described above.

Will you be paid for taking part in this study?

- Parents will be paid $125 for their time and effort. Compensation will be provided periodicially throughout study participation in the form of a participant research card.
- Teen participants will be paid $125 for their time and effort. Compensation will be provided periodicially throughout study participation in the form of a participant research card.
- Additionally, participants will be able to receive $5 for referring a friend to take part in the study. Participants will receive the $5 payment after the friend contacts the study team, says who referred them to the study, and completes the telephone screening. Participants will receive $5 for each referral, for up to 5 referrals ($25 maximum). Compensation will be provided in the form of a participant research card.

We may share your data with third parties (other researchers/institutions or for profit companies). Your data may be used for commercial profit. You will not receive any financial benefit from the use of your data.

If you receive payment using a bankcard, the bank will have access to some personal information in order to process your payment. The bank will not have access to any medical information.

Who is funding this research study?

The Centers for Disease Control and Prevention is providing funding for this study.

Please ask Dr. Allison Curry if you have any questions about how this study is funded.

What if you have questions about the study?

If you have questions about this study or how your data are going to be used, contact the study researcher, Dr. Curry at currya@email.chop.edu or 267-425-1525. You may also talk to your own care team if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

What will be done with my data when this study is over?

As part of this study, we will collect data from you and your child. CHOP will keep these data without identifiers – they cannot be relinked back to you – when the study is completed. The information we collect from you will be given a unique code to help protect your confidentiality. This code will serve as the link between your personal information (such as your name and contact information) and your research data. Only coded research data (without your name or other uniquely identifiable information) will be used for future research.We may use and may share these data for future research. They may be shared with researchers/institutions outside of CHOP. We could also share data with for profit companies (Minnesota HealthSolutions). We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are.

Therefore, you will not receive any results or financial benefit from future research done on your data.

Please indicate whether you will allow the data to be used for future research by putting your initials next to one of the following choices:

_____ (initials of person obtaining consent) NO, my data may only be used for this study and not shared with other institutions or researcher.

_____ (initials of person obtaining consent) YES, my data may be shared and used for other future research studies.

Optional: Contact in the Future

We may wish to contact you and your child again at a later date to obtain follow-up information or for future research studies. Please indicate below with your initials whether or not we may contact you in the future if we have additional questions, updates, or research opportunities.

_____ (initials of person obtaining consent) You may contact me at a later time.

_____ (initials of person obtaining consent) I do not wish to be contacted again at a later time.

For telephone consent:

Documentation of Verbal Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

_____	_____
Name of Parent Subject	Name of Teen Subject

The research study and consent form was explained to:

_____	_____
Person Providing Consent	Relation to subject: ☐ Parent ☐ Legal Guardian ☐ Self (youth 18 years of age)
_____	_____
Person Providing Consent	Relation to subject: ☐ Parent ☐ Legal Guardian

☐ Self (youth 18 years of age)

The person(s) who provided consent confirmed that all of their questions had been answered and they agreed to their/their child's participation in this research study.

They confirmed that they were legally authorized to consent to their/their child's participation.

They agreed to let CHOP use and share their/their child's health information.

Person Obtaining Consent

Signature of Person Obtaining Consent

Date

Documentation of Child Assent to Take Part in this Research Study

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

Person Obtaining Assent

Signature of Person Obtaining Assent

Date