Title:	**Promoting Intrafamily Accountability for Reducing Cellphone Use While Driving in Adults and their Teen Children**
Short Title	Intrafamily Accountability and Cellphone Use
eIRB Number:	15-011835
Protocol Date:	10/6/2016
Amendment 1 Date:	Amendment 3 Date:
Amendment 2 Date:	Amendment 4 Date:

Sponsor

National Institute on Aging (NIA) Penn Roybal Center P30AG034546 pilot grant

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ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	Adverse Event
CHOP	Children's Hospital of Philadelphia
SAE	Serious Adverse Event
UPenn/Penn	University of Pennsylvania
PMACS	Penn Medicine Academic Computing Services
SQL	Structured Query Language
PHP	Hypertext Preprocessor
SSL	Secure Sockets Layer
HTTPS	Hypertext Transfer Protocol Secure
PHI	Personal Health Information

ABSTRACT

Context:

In 2012, 3,328 people were killed and an additional 421,000 were injured in crashes involving a distracted driver[1]. Adults aged greater than 40 years old accounted for 44% of these fatalities[2]. Teen driving behavior is heavily influenced by parental driving behaviors with a recent study showing the proportion of teens that text while driving is 14% higher if they have observed their parents doing the same[4]. The proportion of adults who text while driving has recently surpassed teen rates with a 2013 national poll finding 49% of adult car commuters admit to texting while driving, most stating that they did it out of habit[5]. Based on previous findings, it is unlikely that teens will reduce their texting while driving unless their parents do the same.

Objectives:

The objective of this study is to compare measures of acceptance and feasibility across teen-parent dyads randomized to bidirectional teen-parent (teen monitors parent and parent monitors teen) vs. teen only (parent monitors teen) cellphone use while driving.

Study Design:

Research participants will be recruited to take part in a randomized control trial. Participants' cellphone use will be observed during an initial baseline period. Participants will be randomly assigned to one of two conditions (bidirectional teen-parent monitoring or parental monitoring of the teen only). An exit survey and interview will be administered to both the parent and teen separately at the end of the study.

Setting/Participants:

High school students who are age 16 or 17 at the start of the study that drive an average of 4 or more trips per week and hold a valid driver's licenses and a parent for each teen will be recruited. Other inclusion criteria include living with their teen/parent, having their own smartphone (iPhone 4S or newer or Android 4.3 or newer) with data plan, admitting to texting while driving at least once in the past month, and do not currently use a cellphone blocking app or device, parent willing to install device and adjust settings as necessary.

Study Interventions and Measures:

Cellphone blocking device(s) (Cellcontrol DriveID) will be mailed or given directly to participants for each car driven by the teen and/or parent. DriveID will measure all participant cellphone use while the cellphone is in the car for the first three weeks. During

the intervention period, participants will be randomized to one of the two conditions and followed for 8 weeks. Surveys will also be administered as part of this study.

1. BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

In 2012, 3,328 people were killed in crashes involving a distracted driver; an additional 421,000 people were injured.[1] Adults aged greater than 40 years old accounted for 44% of these fatalities, and drivers under the age of 20 were more likely than any other age group to die in distraction-related crashes caused by cellphone use. According to a CDC survey, 43% of U.S. high school students admit to texting while driving in the last 30 days,[2] despite the majority knowing that this behavior is harmful.[3] It has been well established that teen driving behavior is heavily influenced by parental driving behavior. A recent study demonstrated the proportion of teens that text while driving is 14% higher if they have observed their parents doing the same.[4] Unfortunately, the proportion of adults who text while driving has recently surpassed teen rates with a 2013 national poll finding 49% of adult car commuters admit to texting while driving.[5] Most of these adults surveyed said they did this out of habit, despite 98% also knowing it unsafe, and 60% saying they did not do this three years ago.[5] The emergence of this behavior on a national scale is highly problematic because a meta-analysis of 28 epidemiologic, driving simulator, and naturalistic studies[6] and a New England Journal of Medicine study[7] have found that texting while driving increases the risk of crashing by at least 3- to 4-fold. The U.S. Healthy People 2020 objectives call out distracted driving from cellphone use as the top emerging cause of injury in need of future research.[8]

Novel strategies are needed to address this emerging health risk behavior as legal bans, public awareness campaigns, and pledges to not use a cellphone while driving have had little effect on curbing this behavior.[9] One potential reason these efforts have had limited success is that texting while driving is a behavior shown to be driven by present bias,[10] the tendency to place more weight on benefits realized now and less weight on costs realized in the future, leading to prioritizing immediate pleasure over actions that are in one's long-term interest.[11] Several studies motivated by behavioral economic theory have shown that financial incentives reduce health risk behaviors driven by present-biased preferences such as smoking.[12] However, despite great promise, such incentives have not been trialed for combating texting while driving. Furthermore, given the above findings, it is unlikely that teens will reduce texting while driving unless their parents do the same.

1.2 Name and Description of Intervention

Cellcontrol DriveID was released in December of 2013 as a device to overcome a technological barrier in being able to accurately measure whether a driver's cellphone is being used while driving. It is a solar-powered Bluetooth signaling technology placed on the car windshield. DriveID can measure type of cellphone use while driving and be configured to block a driver's cellphone use while the vehicle is in motion. There is no physical interaction with the DriveID device other than installation.

The device is placed on the windshield and an app is downloaded on to the phone. Online configuration of the device settings takes approximately 3-5 minutes. After the initial installation, the device is always on and interacts with the user's cellphone in the background. Only the cellphone with the corresponding DriveID application is monitored by the DriveID device. The DriveID device directly measures the vehicle's movements and can be set to lock the phone at speeds as low as 1 mph. Device setup is flexible to allow specific smartphone applications like navigation and maps to be used if initiated when stopped. The blocking function cannot be deactivated without permission of the account holder.

The study intervention involves randomization into one of two conditions: teen-parent monitoring and teen only monitoring. In the bidirectional teen-parent monitoring condition, the teen driver will receive an automatic notification (via email) when one of his or her parents overrides the DriveID blocking function to use their phone while driving along with the parent receiving a notification when their teen overrides the blocking function. The teen only monitoring condition only involves the parent/guardian receiving a notification (via email) if their teen overrides the DriveID blocking function. Furthermore, if anyone tampers with the DriveID device, delete the corresponding application from their smartphone, or disable Bluetooth capabilities, an email will be sent to a member of the study team.

1.3 Findings from Non-Clinical and Clinical Studies

The largest, most rigorous study of the crash risk associated with distraction from cellphone use was published in the New England Journal of Medicine in January 2014. The authors conducted two studies on the relationship between the performance of secondary tasks, including cell-phone use, and the risk of crashes and near-crashes. To facilitate objective assessment, accelerometers, cameras, global positioning systems, and other sensors were installed in the vehicles of 42 newly licensed drivers (16.3 to 17.0 years of age) and 109 adults with more driving experience.

During the study periods, 167 crashes and near-crashes among novice drivers and 518 crashes and near-crashes among experienced drivers were identified. The risk of a crash or near-crash among novice drivers increased significantly if they were dialing a cell phone (odds ratio, 8.32; 95% confidence interval [CI], 2.83 to 24.42), reaching for a cell phone (odds ratio, 7.05; 95% CI, 2.64 to 18.83), sending or receiving text messages (odds ratio, 3.87; 95% CI, 1.62 to 9.25), reaching for an object other than a cell phone (odds ratio, 8.00; 95% CI, 3.67 to 17.50), looking at a roadside object (odds ratio, 3.90; 95% CI, 1.72 to 8.81), or eating (odds ratio, 2.99; 95% CI, 1.30 to 6.91). Among experienced drivers, dialing a cell phone was associated with a significantly increased risk of a crash or near-crash (odds ratio, 2.49; 95% CI, 1.38 to 4.54); the risk associated with texting or accessing the Internet was not assessed in this population. The prevalence of high-risk attention to secondary tasks increased over time among novice drivers but not among experienced drivers.

The authors concluded that the risk of a crash or near-crash among novice drivers increased with the performance of many secondary tasks, including texting and dialing cell phones. The study was funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Highway Traffic Safety Administration.

There is one previous field study using Cellcontrol's cellphone blocking/filtering technology to reduce cellphone use while driving, which was funded by the National Highway and Traffic Safety Administration (NHTSA Contract DOT HS 811 863) and carried out by investigators at the University of Michigan. The abstract of the full report published online in December 2013 states:

> Forty-four participants each received a cell phone filtering/blocking application on their employer-provided cell phones for 9 weeks. During the first and last 3 weeks, cell phone activity including calling, text messaging and application use was simply recorded in the background. During the middle 3 weeks, the cell phone filtering/blocking software was active, meaning that anytime the application sensed that the phone was moving faster than the pre-set speed threshold, all phone activity was blocked. Objective data on participants' phone use behavior and subjective data (from a questionnaire) on participants' acceptance were collected. Additionally, the impact on an organization attempting to implement a similar program employing cell phone filtering/blocking was examined. During the blocking period, participants initiated a higher proportion of their calls when stopped than when the blocking software was inactive. Also, during the blocking period, participants answered a much smaller proportion of incoming calls while driving, and outgoing calls were placed at a lower mean speed. Participants were neutral in their opinions on whether they received a safety benefit from the cell phone blocking.

1.4 Compliance Statement

This study will be conducted in full accordance of all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol and will report unanticipated problems involving risks to subjects or others in accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

The purpose of the study is to demonstrate acceptance and feasibility of conducting a field trial of cellphone blocking technology between parents and their teen drivers to calculate sample sizes for future trials and generate preliminary data for funding applications. Primarily, the proposed is measuring whether the bidirectional teen-parent monitoring approach decreases overall cellphone use while driving for both teen and parent.

2.1 Primary Objective (or Aim)

The primary objective of this study is to compare measures of acceptance and feasibility of teen-parent dyads randomized to bidirectional teen-parent vs. teen only monitoring of cellphone use while driving in an on-road driving study.

2.2 Secondary Objectives (or Aim)

The secondary objectives are to:

1. To compare the: a) number of cellphone unlocks per hour of drive time; and b) total proportion of non zero-speed drive time spent using a cellphone while driving in teen-parent dyads randomized to bidirectional teen-parent vs. teen only monitoring of cellphone use while driving in an on-road driving study. These estimates will be used to design a future, well-powered study examining the comparative effectiveness of these two approaches as the primary objective.

2. To determine the drive and environmental characteristics of instances in which a phone is unlocked using data collected from the DriveID device overlayed with data collected from Geographic Information Systems (GIS).

3. Measure the reasons cellphones are being used while driving at non-zero speeds among teens and their parents(calls, texts, smartphone apps, etc.)

4. Measure teen and parent satisfaction with the cellphone monitoring and blocking device

5. Determine the incidence of handheld cellphone use while driving and its relationship to incoming text messages and driving conditions in a teen drivers and their parents.

6. Measure the number of phone unlocks per hour of drive time

7. Measure the speed of the car, acceleration, and spatial characteristics of phone unlocks (ex. on highways vs. at intersections)

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

This is a randomized control study of teen only monitoring vs. bidirectional teen-parental monitoring of cellphone use while driving.

3.1.1 Screening Phase

Interested participants can contact a study team member for more information about the study, and/or, they will be directed to the Way to Health platform for more study information as well as consent. All participants who consent will be contacted by a member of the study team to ensure full comprehension of study procedures and requirements.

Participants will also be recruited through posted flyers, postcards, email blasts, through the Recruitment Enhancement Core (REC), social media, and by word-of-mouth/colleague

referrals at Penn and CHOP. The flyers will be posted in a variety of public and private locations, including but not limited to, local public and private high schools in suburban and local Philadelphia, summer camps, universities, etc. No recruitment will occur through schools or public places without first obtaining permission. Postcards will be mailed to potentially eligible families identified by the REC and the Penn Social Media & Health Innovation Lab.

The Penn Social Media & Health Innovation Lab will assist with recruitment through a variety of social media outlets including Facebook and Craigslist. Language for these postings have been included with the application.

Interested participants will be directed to the Way to Health platform. A parent will create an account and consent online. Once consent is obtained, teens will be able to create their own account and assent online. Once consent and assent are obtained, parents and teens will be screened for eligibility with an eligibility survey presented on the Way to Health platform. Only eligibility criteria will be asked. If a participant responds "yes" to all questions, teens and parents will each be presented with an intake survey on the Way to Health platform. Questions will cover demographics, opinions, perceptions and experiences with texting and driving. Both parent and teen will be asked to email the study team a picture of their driver's license. A member of the study team will also contact the teen to answer any questions and to mail out the CellControl device. If a teen is not eligible, the participant will be informed that they are ineligible for the current study.

If participants turn 18 during the duration of the study, they will be re-consented as an adult through Way to Health.

3.1.2 Baseline Measurement Period (Weeks 1-3)

DriveID will monitor all cellphone use while the participant's cellphone is in the car in which DriveID is installed. During the Baseline Measurement Period, DriveID will only monitor cellphone use while driving; no blocking will occur. During this period the Cellcontrol app runs in the background.

3.1.3 Intervention Measurement Period (Weeks 4-8)

DriveID will monitor all cellphone use while the participant's cellphone is in the car in which DriveID is installed. The application will be used as a cellphone blocking device where the phone will lock the phone screen while driving and block incoming calls and texts. The locking function can be overridden with a tap of a button on the home screen. This use of this application has been approved by IRB proposal 14-11234 for use in a teen driver cohort. DriveID continuously monitors cellphone use while driving, regardless of whether the blocking function is activated, including how often the teen and/or parent unlocks the cellphone as well as if they are using the phone for a call or other handheld phone features. However, DriveID is not able to differentiate which phone features are being used. DriveID will capture GPS data throughout the measurement period. A survey following the baseline period (end of Week 3) will be administered to gain feedback. At the completion of Week 8 or upon voluntary withdrawal from the trial, the participants will be instructed to complete an online survey administered through Penn's Way to Health IT

platform asking about user satisfaction with the device and its configurations. Participants will also be asked to complete a semi-structured phone interview after study completion.

The study team does not promote texting and driving and encourages all participants to drive safely.

3.2 Allocation to Treatment Groups and Blinding

Participants will be randomized to one of two groups. The randomization chart will be maintained will be maintained on a secure server that is only accessible by key study personnel.. Participants and study staff will be aware of which group they have been assigned to.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

The study duration per subject pair will be up to eight weeks.

3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

The study is being conducted at the Children's Hospital of Philadelphia and the University of Pennsylvania. It is expected that a maximum of 250 people will participate in this research study.

3.4 Study Population

3.4.1 Inclusion Criteria

Teen:

1) Is a high school student (age 16 or17 at start of the study)
2) Holds a valid driver's license
3) Lives in parent/guardian's home
4) Primarily drives one car
5) Drives an average of 4 or more trips per week
6) Has their own iPhone 4S or newer or Android 4.3 or newer smartphone with data plan
7) Admits to texting while driving at least once in the last month

Parent:

1) Is the parent of a teen driver
2) Drives an average of 4 or more trips per week
3) Primarily drives one car
4) Has their own iPhone 4S or newer or Android 4.3 or newer smartphone with data plan

5) Admits to texting while driving at least once in the last month

Both parent and teen will be enrolled together as a pair.

3.4.2 Exclusion Criteria

1) Parent and/or teen already uses a smartphone app or hardware device to limit cellphone use while driving

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

4.1 Screening Procedure and Online Consent/Assent Process

Potential participants will be recruited through methods discussed in section 8.5. Teens and parents will be instructed that the parent first needs to create an account through the WTH platform and then review a consent and sign prior to their teen being screened for the trial. Way to Health collects basic demographic information from every person creating an account, including date of birth. After a parent consents for them and their teen to participate, parents will be presented with an eligibility survey. If elibilble, they will be instructed to have their teen go to the WTH site and register. Teens will then review and sign an assent for the trial. Following this they will be screened with an eligibility survey presented on the WTH platform. If a participant is eligible, they will be allowed to continue in the trial and will be asked to complete the intake survey immediately. Questions will cover demographics, opinions, perceptions and experiences with texting and driving. They will then continue on with their trial participation. If they are not eligible, the participant will be informed that they are ineligible for the current study and will not complete any study procedures. These teens will be documented as screen failures. After teen assent and eligibility is completed, parents will be able to sign back into Way to Health and complete the intake survey.

Teens and parents will be asked to email the study team a copy of their driver's license. A member of the study team will then contact the teen and parent/guardian to schedule an in person meeting or a phone meeting. During this meeting the study team will answer any questions pertaining to the consent or the study and distribute the DriveID device in person or by mail. If a participant turns 18 years old during their participation in the study, a member of the study team will email the teen a link to complete the online consent via WTH in order to re-consent. Participants will receive an email or a text message reminder regarding incomplete steps in WTH depending on their preference selection for communication.

The validation of the online consent/assent process will be met during this meeting and allow for the fulfillment of one of the study aims: to demonstrate the feasibility and effectiveness of an online consent process in order to remotely recruit a larger number of participants in future studies among those who purchase the Cellcontrol product. During the meeting, a member of the study team will ensure that the participants truly understand the

risks and benefits of the study. If any participants wish to withdraw, they may do so at this time.

4.2 Device Installation

Parents will install the DriveID device via instructions provided with the device. DriveID devices will be installed in all cars driven by the teen-parent dyad. The DriveID device is installed behind the rearview mirror as to not impede vision of the road; the size of the device is approximately 3 inches by 5 inches. The parent and teen will also complete online registration of the device. When installation is completed correctly, a confirmation message is sent to Cellcontrol. If Cellcontrol receives an error message, noting incorrect installation, a member of the study team will contact participants to troubleshoot.

4.3 Study Treatment Phase

The study treatment phase will consist of a baseline measurement period, an intervention and a debriefing period.

4.3.1 Intervention

DriveID will measure participants' trip characteristics (duration, mileage, speed) and cellphone use while the cellphone is in the car in which the DriveID device is installed. DriveID will also record GPS data. This data will not be accessed in real time by the study team and will only be viewed after the completion of the drive.

Coded data on primary and secondary endpoints will be automatically uploaded daily whenever the phone has a Wi-Fi or cellular data connection to the Cellcontrol server and then exported through an encrypted, secure internet connection to Penn's Way to Health IT Platform for management and analysis via linkage of a study ID (as has been established under IRB 14-11234).

After baseline period, parents can view teen trip summaries.

4.3.2 Debriefing

At the completion of Week 8 or upon voluntary withdrawal from the trial, the participants will be instructed to complete an online survey administered through Penn's Way to Health IT platform asking about user satisfaction with the device. They will receive a link to the survey through email. If necessary, they may receive reminder calls from members of the study team for a one month period following study completion. The purpose of the survey will be to debrief the participant's experience with the trial, cellphone blocking technology, and suggestions for designing a better trial. For subjects that withdrawal prematurely, we will ask about what factors contributed to their decision to withdraw early.

For participants who complete the trial, a member of the study team may contact them to complete a brief, semi-structured exit phone interview.

4.4 Subject Completion/Withdrawal

Participants may withdraw from the study at any time. They may also be discontinued from the study at the discretion of the Investigators at any time.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Confirmation of Eligibility

Members of the research team will confirm the eligibility of potential subjects based on the inclusion/exclusion criteria noted in Section 3.4 during the in-person meeting or phone call, after the online consent/assent process. A parent or guardian will first need to create an account on the Way to Health platform and complete consent online. Once consent is obtained, teens will need to create an account on the Way to Health platform and complete assent. After consent and assent are completed, parents and teens will each be presented with a survey to confirm eligibility. If they are eligible, an intake survey will be available for teens to complete. A study team member will contact participants to confirm eligibility. Confirmation of eligibility will be recorded and retained for all individuals. If subjects are not eligible, no other study procedures will occur.

5.2 Intake Survey

We will collect the following information on the parent participant:

- Demographic characteristics
- Driving habits over the previous 30 days
- Attitudes toward in-vehicle cellphone blocking technologies
- Opinions and perceptions on texting while driving and associated technology
- Preferences and use of wireless technology while driving a vehicle

We will collect the following information on the teen participant:

- Driving habits over the previous 30 days
- Use of in-vehicle cell phone blocking technology
- Opinions and perceptions on texting while driving and associated technology
- Month and Year of Birth

5.3 Cellcontrol Data

Cellcontrol requires users to enter in basic information to set up the account policy. This includes:

- Username
- Password
- Name
- Phone number
- Email

The Cellcontrol app currently tabulates the following data which are uploaded securely to the Cellcontrol server:

- Phone talk time while driving
- Phone usage time while driving (non-talk time phone unlocked and being used for apps, texts, email, etc.)
- Phone unlocks while driving
- Speed the car is traveling when the phone is unlocked
- Incidence of hard decelerations converted to a "driving score" and hard accelerations converted to an "eco score"
- Number of incoming calls and texts that are blocked
- GPS, accelerometer, and timestamp data

5.4 End of Baseline Period Survey

We will collect self-report information on each subject's (both teens and parents) driving behaviors for the previous three weeks in which they were enrolled in the trial study. Information includes how often they report texting and driving and self-report cellphone use.

5.5 End of Study Survey

We will survey participants via the Way To Health platform. The survey will be constructed in Qualtrics, an online survey tool used by Way To Health, to elicit feedback on the cellphone blocking technology. Participants will be asked to report:

- Their feedback on using the cellphone blocking technology
- Feedback on settings/configurations of the cellphone blocking technology
- Perceptions of whether their safety had improved with the use of the technology
- Suggestions for improving the technology and the research study
- Suggestions for future interventions to promote engaged driving

5.6 End of Study Semi-Structured Interview

Approximately 20 teen and 20 parents will be interviewed after completion of the study, Members of the study team will schedule a time to call participants to conduct a brief, semi-structured interview to provide formative data around current strategies to reduce high-risk cellphone use while driving and key elements of an educational, mobile device, and behavioral incentive intervention. The interview will be conducted by a member of the study team and will be recorded by the Penn Mixed Methods Research Lab.

5.7 Safety Evaluation

This is a minimal risk, behavioral intervention study. Physical risk is no more than the risks already caused by distracted driving from handheld cellphone use. The intervention directly lowers the risk of distracted driving by blocking incoming phone calls and texts and locking the phone while the participant is driving. The participant may unlock the phone in any of

the conditions with the tap of a finger where they will then be brought to their typical home screen. If participants have their phone password protected, they will still need to enter their password in order to use the phone. The extra swipe to dismiss the cellphone blocking technology is no more dangerous than unlocking the phone normally.

Participants will have no interaction with the physical DriveID device after installation. There are no expected serious adverse events related to the intervention or participation in this study.

6 STATISTICAL CONSIDERATIONS

This is a pilot trial with the purpose of demonstrating the feasibility of conducting this type of research and generating data in order to estimate sample sizes for future trials.

6.1 Primary Endpoint

In determining feasibility the following endpoints will be measured:

- Proportion of screen eligible who enroll
- Number enrolled per month
- Retention rates by study arm
- Proportion of surveys completed
- Acceptance of cellphone blocking strategy measured on Likert scale in post-study survey

6.2 Secondary Endpoints

Frequency of phone unlocks at non-zero speeds

Total proportion of trip time the phone is in use at non-zero speeds

Total proportion of trip time on non-call related phone use at non-zero speeds

Total proportion of trip time on call-related phone use at non-zero speeds

Total proportion of trip time on non-call related phone use while stopped.

Total proportion of trip time on call-related phone use while stopped.

Seconds of phone use at non-zero speeds

Seconds of phone use while stopped

Number of incoming calls and texts that were blocked

Number of times participants make or receive a phone call, send or read a text message, and use any application while driving at non-zero speeds

Participant acceptance of cellphone blocking technology based on post-study survey

Incidence of handheld cellphone use and its relationship to incoming text messages and driving conditions

6.3 Statistical Methods

6.3.1 Baseline Data

Baseline and demographic characteristics will be summarized by standard descriptive summaries (e.g. means and standard deviations for continuous variables such as age and percentages for categorical variables such as gender).

6.3.2 Efficacy Analysis

The primary analysis will be based on an intention to treat approach and will include all subjects randomized at the beginning of the intervention period.

Primary endpoints on feasibility and acceptability will tabulated across randomization arms using descriptive statistics.

Secondary efficacy endpoints will summarized with descriptive statistics across arms and will include:

Frequency of phone unlocks at non-zero speeds

Total proportion of trip time the phone is in use at non-zero speeds

Total proportion of trip time on non-call related phone use at non-zero speeds

Total proportion of trip time on call-related phone use at non-zero speeds

Total proportion of trip time on non-call related phone use while stopped.

Total proportion of trip time on call-related phone use while stopped.

The statistical model used for the efficacy analysis will be tailored to the selected endpoint, but will likely be evaluated with a multilevel model to examine within-subject and across-subject changes over time.

A secondary epidemiologic analysis will examine the driving and environmental characteristics associated with the instant a phone is unlocked at non-zero speeds. This will include vehicle speed, acceleration, time of day, and road and weather characteristics based on GPS location of the phone unlock.

STUDY INTERVENTION

6.4 Description

The study intervention will involve two different conditions to which participants may be randomized.

6.4.1 Teen-Parent Monitoring Group

The blocking settings will turn on by default while driving. Blocking settings will be pre-set to block all incoming calls and text messages while the vehicle is in motion, but participants will have the ability to override the blocking. Number of unlocks can be monitored through logging in to the Cellcontrol website.

In the bidirectional monitoring arm, the teen will receive an email notification when their parent unlocks their phone while driving and vice versa.

6.4.2 Teen Only Monitoring Group

The blocking settings will turn on by default while driving for both the teen and parent. Blocking settings will be pre-set to block all incoming calls and text messages while the vehicle is in motion, but participants will have the ability to override the blocking. Number of unlocks can be monitored through logging in to the Cellcontrol website.

The teen only monitoring group involves parental monitoring of teen's cellphone use while driving only. The parent will receive an email notification when their teen unlocks their phone while driving. Both parent and teen will drive under the same restrictions, but only the parent will be notified of teen cellphone use.

7 SAFETY MANAGEMENT

7.1 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

Enrolled participants will be provided with contact information of a study team member for reporting of any adverse events that occur during data collection. They will be told to contact regarding any occurrence they feel is an adverse event, including but not limited to, moving violations/citations while participating, traffic accidents, DriveID malfunction, etc.

8 STUDY ADMINISTRATION

8.1 Treatment Assignment Methods

8.1.1 Randomization

Participants will be randomized to one of the two condition groups. A statistician who is not involved with enrolling subjects will be responsible for creating the randomization chart. We will do block randomization for 4 assignments at a time. Each block will contain the two arm assignments repeated once in a random order. We will create a string that is 250 assignments long. As participants reach the intervention phase they will be assigned to the next available assignment in this string. Once an assignment has been used it is no longer available to be used. Study staff and participants will not be blinded to the condition. Individuals conducting data analyses will use data which blinds them to which group participants are in..

8.2 Data Collection and Management

Confidentiality, Security, and Anonymization

8.2.1 Way To Health

All personal information that the participant is asked to provide will be collected via *Way To Health. Way To Health* collects subjects' names, dates of birth, addresses, email addresses, phone numbers, and the last four digits of their social security number. They also request the name and phone number of an alternate contact. To assure that participant confidentiality is preserved, individual identifiers are stored in a single password protected system that is accessible only to study research, analysis and IT staff. The last four digits of participants' social security numbers will be stored in a locked cabinet to be destroyed at a later date. An investigator or statistician who logs in will be able to access only non-identifiable data. The *Way To Health* administrative group and research coordinators responsible for contacting participants for follow-up study visits or responding to questions about the study are able to view participant names and contact information. The WTH web development team and Project Director currently have administrative access to PHI. All of these personnel will have completed Human Subjects Protection and HIPAA privacy training. The system automatically generates logs of all data queries which can be reviewed by research staff to ensure that no unauthorized persons have gained access to identifiable information. This system is hosted on site at The University of Pennsylvania (UPenn) and is protected by a secure firewall and several layers of operational security. Once a participant has been entered into this system, they are given a unique study identification number (ID). Any datasets and computer files that leave the firewall are stripped of all identifiers and individuals are referred to by their study ID. The study ID is also used on all analytical files.

The Penn Medicine Academic Computing Services (PMACS) is the hub for the hardware and database infrastructure that supports the project and the *Way To Health* web portal is built on this infrastructure. The data collected for *Way To Health* based studies is stored in mySQL databases on a PMACS-operated blade server environment devoted specifically to *Way To Health*. The data center is housed in Information Systems and Computing at 3401 Walnut Street. All data are stored in a single relational database, allowing researchers to correct mistakes. Every SQL transaction, including accessing and changing data, is logged for auditing purposes. Data are entered into the database through several different mechanisms. Participants enter their own personal information and respond to surveys through a PHP-based web interface. Researchers have a separate interface that allows them to manually enter data if needed. Datasets are stripped of all personally identifiable information when exported for analysis. The web application automatically removes all identifiers when a researcher requests an analytic dataset. The only people with access to identifiable participant information are pre-specified Research Coordinators responsible for contacting participants for follow-up. Personal information and research data will be stored in separate SQL tables and will be linked by a computer-generated ID number. Additionally, any information that leaves this system to communicate with third party data sources (i.e. survey software) is stripped of any identifiers and transmitted in encrypted format. The same unique study ID is used to link these outside data to the participants. All data for this project will be stored on the secure/firewalled servers of the PMACS Data Center, in data files that will be protected by multiple password layers. These data servers are maintained in a guarded facility behind several locked doors, with very limited physical access rights. They are also cyber-protected by extensive firewalls and multiple layers of communication encryption. Electronic access rights are carefully controlled by UPenn system managers.

Way To Health uses highly secure methods of data encryption for all transactions involving participant's financial information using a level of security comparable to what is used in commercial financial transactions. This multi-layer system of data security, identical to the system protecting the University of Pennsylvania Health Systems medical records, greatly minimizes the risk of loss of privacy. All communications between users and our site will be encrypted with SSL/HTTPs technology.

8.2.2 Cellcontrol

Data collected by Cellcontrol through the DriveID device will be manually uploaded by members of the study team or directly to Way to Health through secure CSV reports. Data will not be tracked in real time.

8.2.3 Semi-Structured Interview

The semi-structured interview will be completed by a member of the study team and will be recorded by Penn's Mixed Methods Research Lab. The MMRL provides verbatim transcription of individual and group data through *Accurate, Dependable, Affordable* (ADA) transcriptions services. ADA provides secure and confidential data transfers consistent with the University of Pennsylvania's Institutional Review Board data safety standard. ADA provides transcription services that are also consistent with federal Health Insurance Portability and Accountability Act (HIPAA) guidelines and regulations. The MMRL works with ADA to check for accuracy. Once accuracy in transcription is determined, original recordings are destroyed.

8.3 Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies on subject privacy and the Investigator and other site personnel will not use such data and records for any purpose other than conducting the study. Participants may be contacted regarding future center events or research opportunities if they consented that a member of the study team can contact them in the future on the consent form. The safeguards described above in Section 8.2 will be implemented to ensure subject confidentiality.

No identifiable data will be used for future studies without participant's consent for future use of data and without first obtaining IRB approval. The investigator will obtain a data use agreement between provider (the PI) and any recipient researchers (including others at CHOP) before sharing a limited dataset (dates and zip codes).

8.4 Regulatory and Ethical Considerations

8.4.1 Data and Safety Monitoring Plan

While there is no data monitoring safety board in place for this study as it is a study with minimal risk and without medical or biological intervention, the research teams at the University of Pennsylvania and the Children's Hospital of Philadelphia, led by the Investigators, will be aware of and will monitor possible areas of risk to the research participants. Weekly team meetings will include discussion of any safety and data issues that are observed. The PIs will be responsible for monitoring the data and safety.

8.4.2 Risk Assessment

Despite care taken in the study design to minimize risk exposure to participants, it is acknowledged that there is minimal risk to participants.

Loss of confidentiality is a potential risk of participating in this study; however, the safeguards put in place by *Way To Health* (Section 8.1) will reduce this likelihood. The members of the study teams will follow necessary precautions to ensure that all collected data is not shared with unauthorized individuals or groups.

As part of this study, teens will be driving with a cell phone blocking device present and operating in the vehicle. These teens are eligible for the study because they admit to texting while driving. This study will not require them to interact with their phones while driving any more than they would normally choose to on their own. We will encourage participants throughout the study to drive safely and not to use their cell phones while driving.

It is possible that participants may feel uncomfortable answering some of the interview questions. They will be made aware before the start of the interview that this is a risk associated with participation in the interview and will be reminded that they do not have to answer any questions which make them uncomfortable.

8.4.3 Potential Benefits of Study Participation

There are no direct benefits from participating in this study.

8.4.4 Risk-Benefit Assessment

The gathered information has the potential to increase the understanding of teen's and parent's opinions on cellphone blocking technology. The research has the potential to enhance the foundation of behavioral change models and improve the quality of continuing education about safety. The results may also speak to the benefits of using cellphone blocking devices in-vehicle for promoting positive safety behaviors; these benefits outweigh the minimal risk of participation in this study.

8.5 Recruitment Strategy

Potential participants will be recruited through a variety of strategies. As we are not limited by geographic location we will perform all recruitment strategies on a national level unless otherwise noted. These strategies consist of on-the-ground recruitment strategies (posting posters and flyers in visible areas, recruitment through local school districts), direct mailer (email blasts, letter or postcard sent to home address), social media (facebook, craigslist, snapchat, etc), for-profit and nonprofit organization partnerships/mentions, media attention (mentions in local and national news sources), and word-of-mouth referrals.

On-the-ground recruitment strategies include posting flyers in areas where teen drivers and parents frequent and recruiting through local school boards. These locations will include parks, malls, and other after school hangouts. These materials will only be posted in the Philadelphia area rather than nationwide. We will also reach out to local school boards to ask about having flyers posted and/or sent to parents in the Philadelphia. We will contact

persons in in the district superintendent office to investigate whether they will be willing to post theses flyers at schools in their district and/or are willing to mail letters to parents of teen drivers in their school district. This will only be done in the Philadelphia area. No recruitment will occur through schools or public places without first obtaining permission. Letters, postcards, and flyers will consist of the messaging in the letters, postcards, and flyer we have attached to this protocol.

We will also recruit participants by mailing letters and doing email blasts to parents of teen drivers. We will work with CHOP's Recruitment Enhancement Core (REC) to contact individuals who have visited CHOP and who have teen drivers through direct mailers of letter and/or postcards. The REC will also send email blasts to families on our behalf. These emails will consist of the messages included in the letters attached to this protocol. Recruitment efforts will include sending mailings in addition to the REC contacting them through email. Investigators will also obtain mailing labels with potential subjects' names and addresses for recruitment letters from the REC.

Social media sources will also be used for recruitment purposes. We plan to use Facebook, Craigslist, Twitter, Snapchat, Google, and Instagram in our social media campaign. The Penn Social Media & Health Innovation Lab will assist us in using the various social media outlets so that we can be as effective as possible in disseminating the recruitment message to the correct population. With many of these mediums we will be able to target teens and parents with separate ads. In those cases we will provide recruitment ads that are targeted for that specific population. In many cases the social media ad that we can use consists of a brief message (i.e., Twitter only allows a 160 character message). In these cases the message would direct the potential participant to the WTH landing page where they can register. On this page we will recreate the full message that is included in the recruitment letters so that all participants are well informed of the study details prior to registering for the study. Final advertisements and Twitter messages have been attached to this protocol.

The use of social media in this trial will include only IRB approved advertisements. These advertisements will be used on social media in a manner that does not allow commenting, posts, or conversation. They will be posted in a way that they will appear like any other advertisement. We will not be creating any social media site where posts or comments can be made (such as a facebook site) instead we will only commence with advertising this study on social media in a form where we will not have to monitor chats and comments. Only IRB approved study staff can post these ads on these sites, after discussion with the study team.

We will be reaching out to many for profit and nonprofit organizations that might be willing to help us advertise this study. These organizations include but are not limited to MADD, insurance companies, and cell phone companies (other examples: madd.org<http://madd.org>, vsofa.org<http://vsofa.org>, stoptextsstopwrecks.org<http://stoptextsstopwrecks.org>, aaafoundation.org<http://aaafoundation.org>, enddd.org<http://enddd.org>, digitalresponsibility.org<http://digitalresponsibility.org>). We will ask these organizations if they would be willing to advertise to consumers using the flyer, letter, or brief mentions on their websites. Letters and flyers would be the same as those used for other recruitment strategies. Brief mentions would redirect potential participants to the WTH landing page where they would read the full recruitment message.

We will be working with the CHOP ad UPenn media relations offices to learn various ways we might get mentions for this study in the press. We hope that some local and nationwide news outlets (Penn News Today, NPR, and other print and online newsletters) will be interested in doing a story on the goals of this program and that this media attention will help with recruitment. If we are successful in getting media attention the lead Penn PI for this study, Kit Delgado, will conduct interviews and ensure that a link to the WTH landing page is included in any material produced around the study.

While all the above recruitment strategies may differ in terms of their approach, message length and type, each method will direct all potential participants either to the WTH landing page where a standard message giving an overview of the program will be posted, or to contact the study team for more information and instructions for how to enroll (via the Way to Health website). That landing page text has been included in this protocol as well. It is important to stress that because of this method all potential participants will be exposed to the same recruitment message and study information prior to registering for the program.

The Recruitment Enhancement Core provides assistance with recruitment plan development and will identify and contact potential participants on our behalf using the CHOP Data Warehouse, and the CHOP Recruitment Registry.

8.6 Informed Consent/Assent

We will require parental consent and teen assent for this trial. Parental consent and subject assent for this trial will be obtained via Way to Health. Interested participants will be directed to the Way to Health Platform to get more information on the trial and complete the online consent/assent process.

Teens and parents will be instructed that the parent first needs to create a username and password through the WTH platform and then review a consent and sign prior to their teen being screened for the trial. After a parent consents for themselves and their teen to participate, they will be presented with the eligibility survey. If eligible, they will be instructed to have their teen go to the WTH site and register. Teens will then review and sign an assent for the trial. Following this they will be screened with an eligibility survey presented on the WTH platform. If a participant is eligible, they will be allowed to continue in the trial and will be asked to complete the intake survey immediately. Questions will cover demographics, opinions, perceptions and experiences with texting and driving. They will then continue on with their trial participation. If they are not eligible, the participant will be informed that they are ineligible for the current study and will not complete any study procedures. These teens will be documented as screen failures. If a teen assents and is eligible, parents will then sign back into Way to Health to complete the intake survey.

A member of the study team will then contact the teen and parent/guardian to schedule an in person meeting or a phone meeting. During this meeting the study team will answer any questions pertaining to the consent or the study and distribute the DriveID device in person or by mail. If a participant turns 18 years old during their participation in the

study, a member of the study team will email the teen a link to complete the online consent via WTH in order to re-consent. Participants will receive an email or a text message reminder regarding incomplete steps in WTH depending on their preference selection for communication.

The validation of the online consent/assent process will be met during this meeting and allow for the fulfillment of one of the study aims: to demonstrate the feasibility and effectiveness of an online consent process in order to remotely recruit a larger number of participants in future studies among those who purchase the Cellcontrol product. During the meeting, a member of the study team will ensure that the participants truly understand the risks and benefits of the study. If any participants wish to withdraw, they may do so at this time.

A member of the study team will contact all enrolled participants to ensure understanding of study procedures. Electronic signatures will be obtained for both parent and child.

8.7 Payment to Subjects/Families

8.7.1 Payment for time and inconvenience (i.e. compensation)

Teen participants will be compensated up to a total of $110 and parent participants will be compensated up to a total $110 for their time, effort, and inconvenience over the duration of the study:

- Teen Intake Survey : $20
- Parent Intake Survey: $20
- End of Baseline Survey Teen: $30
- End of Baseline Survey Parent: $30
- End of Study Survey Parent: $40
- End of Study Survey Teen: $40
- Exit Interview Parent: $20
- Exit Interview Teen: $20

Each enrolled participant will also be able to refer up to 5 people to our study to receive a referral bonus of $5 for each person.

8.7.2 Gifts

Participants will receive a DriveID device for participation in the study. DriveID devices will be installed in all cars driven by the teen-parent dyad, so the number distributed to each family will depend on how many cars they drive (up to 3).

9 PUBLICATION

We plan to publish the findings in conference proceedings and/or peer-reviewed journals.

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