Title:	Sensor Network with Active Instructional Content to Prevent Child Safety Seat Misuse Phase II
Short Title	Cellular Car Seat (CCS) Study
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Sponsor
Minnesota HealthSolutions Corporation
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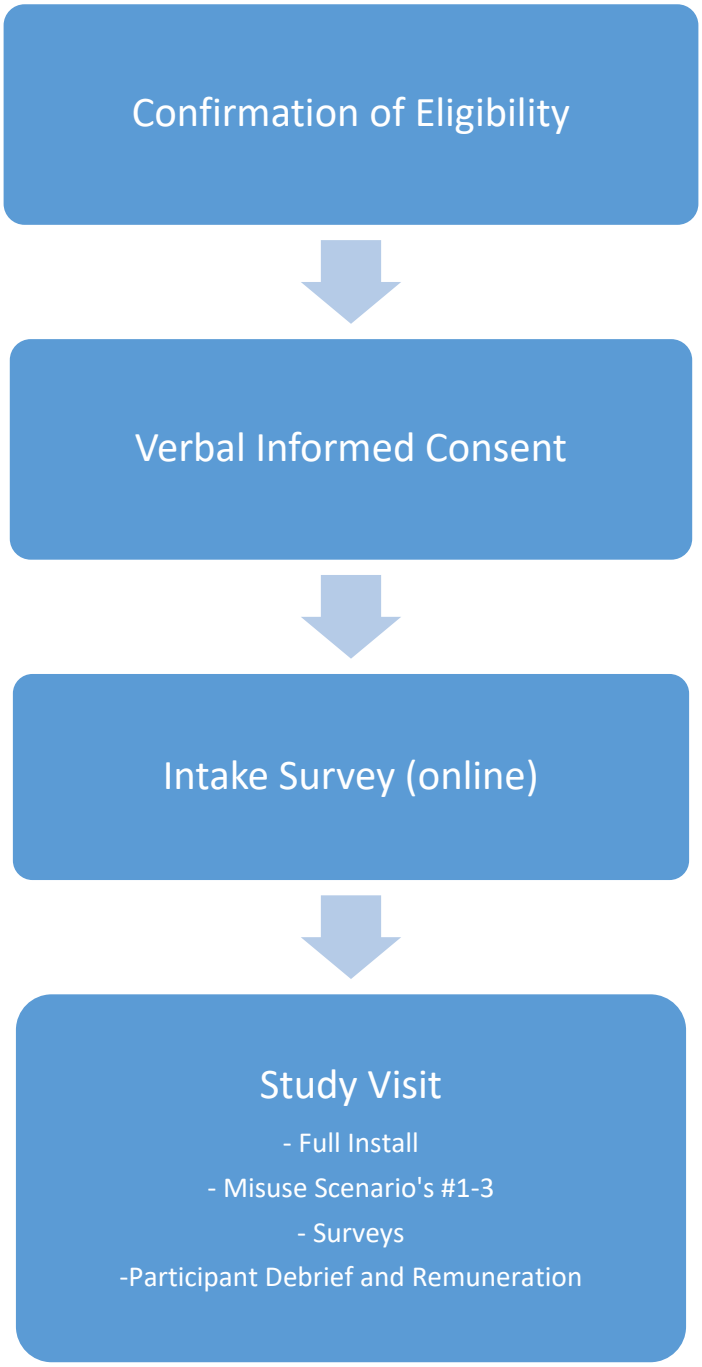
USA

Study Principal Investigator
Allison E. Curry, PhD, MPH
The Children's Hospital of Philadelphia
2716 South Street, 13th Floor
Philadelphia, PA, 19146
Phone: 267-425-1525
Email: currya@email.chop.edu

FIGURE 1: STUDY DIAGRAM



INVESTIGATIONAL PLAN

General Schema of Study Design

3.1.1 Screening Phase

Participants in the CHOP care network will be mailed/e-mailed a letter inviting them to participate in the study. Interested participants can contact the study team using a dedicated e-mail address and phone number. Participants will verbally complete our eligibility screening survey over the phone with a study team member. The solicited information from the eligibility screening survey will be limited to the minimum necessary (e.g., just the inclusion/exclusion criteria) for screening/determining eligibility for the main study and the screening will be brief in duration. Therefore, consent does not apply.

3.1.2 Study Treatment Phase

Eligible participants will be asked to verbally consent to study procedures over the phone. Verbal consent will be documented in REDCap. Once the participant is enrolled, they will be allocated to either the control or intervention group. A research assistant will send the participant an invitation to complete the Intake Survey via REDCap prior to the study visit. If participants have not completed this intake survey prior to their study visit, they will be asked to complete the survey in-person before moving on to the intervention phase.

There will be a one-time study visit, which will take place in a study room on the 4th floor of the Roberts Center for Pediatric Research. The intervention phase of the visit will take place in a study room on the 4th floor.

A member of the study team will meet the participant in the Roberts Center for Pediatric Research parking lot or lobby. The study team member will escort the family to the 4th floor study room. Next, the team member will explain the click tight car seat system and demonstrate it to the participant. The participant will then be asked to do a full install of the car seat prior to completing the misuse scenarios. The participant will then be asked to complete three misuse scenarios. Participants in the intervention group will use the app while participants in the control group will complete the scenarios without the app.

Misuse scenarios will be evaluated by a member of the study team, including measuring harness tightness with a load cell and the pinch test (this will be a yes/no formatted question indicating whether the harness passed the slack test) and asking the participant to see the app once they are finished the scenario. In addition, after each misuse scenario is complete, participants will be asked to complete a brief survey about their experience. Participants will also complete a brief interview at the end of their study visit to understand more about their preferences.

While the first 10 or fewer participants are enrolled, all of the above study procedures will be evaluated to understand any complications of using the prototype convertible child safety seat or collecting data that we may have not predicted (e.g., not understanding how to read the indicator lights). Therefore, we will be monitoring incoming data closely over the first few weeks of the study. If any complications related to the technology or data collection methods arise, we will work to solve the issue for the participant(s) and subsequently determine how best to prevent this complication to future participants. Considerations for statistical implications of using these data are explained in Section 6.3.2 Statistical Considerations.

Allocation to Treatment Groups and Blinding

This study will use a control and intervention group. Each enrolled participant will experience each of the three misuse scenario’s once.

Study Duration, Enrollment and Number of Sites

Duration of Study Participation

Enrolled participants will be asked to complete one online intake survey, lasting up to 20 minutes, and one study visit, which may last up to 90 minutes, including their post-installation interview.

Total Number of Study Sites/Total Number of Subjects Projected

CHOP is the only investigative site for this research study.

It is expected that approximately 100 participants will be enrolled to produce at least 90 evaluable participants.

Study Population

We will seek to recruit at least 25% fathers and ensure a diverse sample of socioeconomic and racial diversity.

Inclusion Criteria

Participant/Guardian

1) Males or females age 18 to 75 years
2) Has harnessed/fastened a child into a car seat in the last 5 years
3) Valid drivers license

Exclusion Criteria

Participant

1) Participant is not fluent in written and/or spoken English
2) Participant cannot install a safety seat due to a physical limitation

STUDY PROCEDURES

Pre-study Visit

Screening/Verbal Consent

A member of the research team will begin by explaining the study to the participant. The participant will be asked if they are interested in participating in the study. If interested, the screening questionnaire will be administered to determine eligibility. Eligible participants will be asked to consent to study procedures.

Self-administered Intake Survey

Participants will receive an invitation to complete the intake survey at their convenience, prior to their study visit. Participants will receive both email and phone reminders if the survey has not been completed in advance of their scheduled study visit. The intake survey will be hosted within REDCap. If participants have not completed this intake survey prior to their study visit, they will be asked to complete the survey in-person before moving on to the intervention phase.

Study Visit

Study visits will take place at the CHOP Roberts Center for Pediatric Research and will not exceed 90 minutes. The following events will take place at the study visits:

Click tight technology explanation by study staff

Initial car seat install- baseline

First misuse scenario

- Study team assessment
- Reaction Survey

Second misuse scenario

- Study team assessment
- Reaction Survey

Third misuse scenario

- Study team assessment
- Reaction Survey

Preference and Experience interview

Participant debrief

Provide participants with remuneration for time and effort

Subject Completion/Withdrawal

Subjects may withdraw from the study at any time. CHOP employees will be included as possible study participants because many of them are within the study inclusion criteria. To ensure that their study participation is completely voluntary, subjects will be assured that their participation is completely voluntary and taking part in this research is not a part of their CHOP work or duties. The Investigator may withdraw subjects who violate the study plan, or to protect the subject for reasons of safety or for administrative reasons. It will be documented whether or not each subject completes the clinical study. If the Investigator becomes aware of any serious, related adverse events after the subject completes or withdraws from the study, they will be recorded.

Early Termination Study Visit

If a participant withdraws at any point during the Study Visit, they will receive full compensation for their time and effort. If a participant withdraws prior to the study visit, they will not receive compensation.

STUDY EVALUATIONS AND MEASUREMENTS

Screening and Monitoring Evaluations and Measurements

Initial Contact

Potential participants who learn about our study through our recruitment efforts may reach out to the study team if they are interested in participating. They may email or call the study team and leave their contact information. Information may include: First and Last Name, Phone Number(s), and Email Address(es). Potential participants are not required to provide this information during their initial contact with the study team; however, if provided, this information will be collected by the study team to aid in further communication efforts.

1.1.1 Screening & confirmation of eligibility

Study research staff will contact participants who respond to our recruitment efforts by phone. These trained staff members will describe the intent of the study and what is involved for the participant. The participant will be invited to complete a brief, preliminary screening survey in order to determine eligibility for the study. The solicited information from the eligibility screening survey will be limited to the minimum necessary (e.g., just the inclusion/exclusion criteria) for screening/determining eligibility for the main study and the screening will be brief in duration. Therefore, consent does not apply.

Each screened participant will need to supply their contact information. The following information will be collected separately from all other measures:

- Participant First Name
- Participant Last Name
- Home Address
- Zip Code
- Phone Number(s)
- Email Address(es)
- Contact preferences (e.g., time of day and mode)
- Participant Date of Birth

After collecting the information, the research team will assign each participant a unique identification (UID) number. This UID will serve to code all subsequent data collection tools.

Members of the research team will confirm the eligibility of potential participants based on the inclusion/exclusion criteria noted in Section 3.4. If the participant chooses not to continue, they will be thanked for their time. Confirmation of eligibility will be recorded and retained for all participants using the UID.

Verbal Consent

Participants who confirm eligibility and interest in participating will then be asked to verbally consent to study procedures. A member of the research team will explain the study to the participant and answer any questions they may have. Documentation of verbal consent will be recorded and retained for all participants. Once the participant is enrolled, they will be invited to complete an intake survey, and scheduled for their study visit.

5.1.4 Intake Survey

All participants will complete an intake survey that will collect data on a variety of car seat measures - current use, behaviors, knowledge, and preferences; and basic sociodemographics. Measures will include:

- Age (years)
- Sex
- Race/Ethnicity
- Self-reported crash history of self
- Household income
- Previous experience installing safety seats and harnessing children into them
- Risk perceptions about child occupant safety
- Barriers and facilitators to safety seat use
- Knowledge and attitudes about existing child occupant safety programs and policies

Efficacy Evaluations

5.2.3 Harness Installations & Assessments

Each participant will complete three (3) misuse scenarios using child safety seats during the study visit.

The assessment of each misuse scenario (n=3) will capture the following information:

Method of harness (e.g., direction of pull to tighten, if the participant checks the tightness or makes adjustments, if participant asks child about tightness)
Length of time (in seconds) to harness
Tightness of harness in control seat (measured by a load cell and pinch test)
Tightness of harness in intervention seat (measured by the number of lights achieved in tensioning, a load cell and pinch test)
Difficulties observed (e.g., participant is unable to get child to cooperate, participant is unable to tighten harness because of physical limitations, or angle of seat makes it difficult to harness child)
Errors present at end of scenario
A series of questions for the participant on their experience during the scenario

1.1.2 Post-observation interview

We will collect the following information from each participant in an interview format after completing all zthree scenarios. Surveys may be collected via paper or direct data entry into REDCap. Interviews may be recorded on video.

- Facilitators or barriers they experienced while installing and harnessing the doll into the seat
- Ease of installation and harnessing
- What they liked or did not like about the app
- Belief of correct instillation and harnessing technique
- Perceived errors in each scenario

STUDY DEVICE

Description

The proposed innovative child safety seat user engagement system designed to actively educate, instruct and alarm caregivers with information associated with automatically-sensed safety seat misuses/errors is highly innovative and address an important unmet need. The goal is to prevent child safety seat critical misuses and reduce deaths and injuries in children riding in motor vehicles. Critical misuses are a major public health concern and include: improper child weight for seat type, improper seat orientation, insecure attachment of the seat to the vehicle, and insecure harnessing of the child. Parental education, how, when, or where parents learned to install seats, and improved graphics/labeling on seats/manuals have been observed to have no significant effect on many critical misuses. Better systems are needed to improve the rate of proper seat use.
A key enabling technology that makes the proposed sensor system possible at this time is newly-available extremely low-cost cellular radio modules that can achieve secure internet connectivity directly from the seat. This cellular radio will be built into an inexpensive pre-configured sensor system capable of sensing key state-of- use information, including the most common critical misuses, to automatically push usage and environmental information to a cloud-based server. The use of cellular technology eliminates the need for users to pair the seat with a cell phone or wi-fi network to achieve connectivity: the sensor system will operate right out of the box.

SAFETY MANAGEMENT

Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the 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.

STUDY ADMINISTRATION

Treatment Assignment Methods

Randomization

Participants will be randomly assigned to either the intervention group or control group upon their arrival to the study visit. The randomization sequence was generated using SAS software, version 9.4 (SAS Institute, Cary, NC, USA).

Confidentiality

All data and records generated during this study will be kept confidential in accordance with CHOP Institutional policies and HIPAA on subject privacy.

The Investigator and research staff will not use such data and records for any purpose other than conducting the study. The research staff will utilize safeguards to protect subject confidentiality, including assigning a UID to each subject and keeping identifiable information separate from all other coded study measurements.

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

Potential Benefits of Participation

Participants may benefit indirectly through the findings from this study that may help to improve correct use of child safety seats.

At the end of the study visit, participants will be provided with resource sheet with some tips and links to resources about how to correctly harness a child into a child safety seat, such as the CHOP site: https://www.chop.edu/centers-programs/car-seat-safety-kids. Participants will not receive custom feedback about their harness installation, since not all members of the study team are certified Child Passenger Safety Technicians.

Risk-Benefit Assessment

There are very minimal risks involved with participating in this study. There may or may not be any direct benefits for participating in this study. There is a possibility that a loss of confidentiality may occur as a result of participating in this study. However, this risk will be minimized by removing all individually identifiable information from any study reports, publications or presentations (see section 9.2 for further details on data storage and protection). Therefore, the potential direct and/or indirect benefits of participation exceed the minimal risk of participation.

Recruitment Strategy

Participants will be recruited using a variety of methods. Our primary recruitment mechanism will be the CHOP Recruitment Enhancement Core (REC). The REC will e-blast possible participants with necessary recruitment information. We may also use the Pediatric Research Consortium (PeRC) for additional recruitment if needed to attain the sample size needed. Additionally, flyers and tear-pads may be posted in areas frequented by individuals in target groups (e.g., local shopping areas where allowed, on CHOP campus) as well as on websites and social media. The ad which has been prepared for websites will be posted on a number of websites frequented by local residents of our target population, including (but not limited to): CHOP network website and other CHOP affiliated sites and Facebook. Lastly, an email blast will be sent to a large portion of faculty and staff as well as other members of the CHOP care network.

Informed Consent/Assent and HIPAA Authorization

Eligibility Screening Conversation

To effectively screen participants and to ensure inclusion and exclusion criteria are met prior to study visit scheduling, a waiver of documentation of screening consent has been requested. Study staff will only collect the minimum necessary information to determine eligibility. Participants will be given a detailed description of the study and have the opportunity to indicate whether they are interested in continuing to the consenting procedures.

Main Study Consent

Participants will provide informed consent over the phone before completing the intake questionnaire. The study will use a combined Informed Consent Form/HIPAA Authorization. Verbal consent will be documented in REDCap. Participants will be able to print or receive an e-mailed copy of the Informed Consent Form/HIPAA Authorization. It will explain all relevant study procedures and provide contact information for study staff. The research presents minimal risk to participants and involves no procedures for which written consent is normally required outside of the research context.

The research staff will encourage subjects to ask questions regarding the study and consenting process. Participants will have as much time as needed to make a decision regarding participation. Participation will be strictly voluntary and participants can withdraw for any reason at any time. As part of the consenting process subjects will be given the option to provide permission for future use of collected data and for future contacts by CHOP about upcoming research opportunities or other events.

Payment to Subjects

Reimbursement for travel, parking and meals

Parking vouchers will be provided to each study participant. The cost for the study team to purchase one of these vouchers if $5/voucher, but no costs will be incurred by the participant. Participants will not be reimbursed for their travel to the Roberts Center for Pediatric Research and no meals will be provided given the brevity of the visit.

Payments to participant for time and inconvenience (i.e. compensation)

Each participant will be compensated for their participation in this study. Following completion of the study visit, or withdrawal during the study visit, participants will be compensated $50. Remuneration will be provided in the form of a CHOP-issued participant research card.

PUBLICATION

CHOP and MHS investigators will have complete access to all study data and will publish results of the study in the form of manuscripts which will be submitted to the peer-reviewed scientific literature in journals relevant to the topic area.