Official Title: Phase II - Safety-Enhancing Motor Vehicle Child Safety Seat

NCT Number: NCT06384989

Document Date: May 2024

Document Contents: Study Protocol and Statistical Analysis Plan

Study Protocol and Statistical Analysis Plan

Background

Engineers from our Small Business partner, Minnesota HealthSolutions, have designed a new prototype child car safety seat. The car seat includes a load leg, which is a relatively new feature that braces the base of the car seat against the floor of the vehicle. The load leg helps to absorb crash forces and prevent movement of the car seat and its occupant during a crash. Load legs already exist on a few car seat models on the market today, but Minnesota Health Solutions has created a new design that absorbs energy in a novel way.

The research team from the Ohio State University (OSU) was involved in a Phase I SBIR with the prototype car seat. In that project, the prototype was shown to 15 volunteer participants (12 caregivers and 3 certified Child Passenger Safety Technicians (CPSTs)). The study participants practiced installing the car seat and gave verbal and written feedback on the understandability and ease-of-use of the load leg. They provided information about their families' travel habits and whether they saw value in the newly designed feature.

In this Phase II SBIR proposal, OSU will conduct additional human subjects testing to gauge the usability of the new car seat safety feature in a more in-depth and quantitative approach.

Objectives

The primary objective is to assess the usability of the load leg design for caregivers who must install the child safety seat into a vehicle. The specific aims are to quantify any errors committed by the participants while installing the car seat and to assess participants' opinions on the car seat's load leg design.

Research design

A descriptive study will be conducted to determine whether human subjects are able to install the new feature of the prototype car seat correctly. Participants will be presented with the prototype car seat and a set of basic written instructions and labels to guide their installations. The percentage of participants who use the new feature and use it correctly will be reported. Any installation errors on other parts of the child seat (seat belt, lower anchors, top tether) will also be reported.

Detailed study procedures

Recruitment

Announcements will be posted in OSU employee newsletters, volunteer mailing lists, department mailing lists, and social media. Interested participants will be asked to email the study team. Study personnel will send a response email to determine if the participant is eligible to participate. Pre-screen questions will identify potential participants who meet the following criteria:

1. Age 18 or older
2. Be a care provider to a child who is up to 2 years of age
3. Have installed a child safety seat in the last 2 years
4. Able to lift and install a child safety seat into a vehicle
5. English-speaking

Participants who meet the above criteria will be asked to schedule an individual appointment.

Enrollment

Participants will be enrolled for one 30 minute time slot. Upon arrival at the scheduled time, participants will be briefed on the study protocol, sign the IRB approved consent form, incentive payment receipt, and will be given the incentive payment.

Session Protocol

Each participant will complete the consent process and sign the consent form. The participant will be asked to install the prototype car seat into a vehicle. A basic set of written instructions and labels on the car seat will be provided. The researcher will explain that they cannot answer any questions during the installation and that the participant may take as long as needed. If a participant completes the installation without using the load leg, this outcome will be noted and then the participant will be prompted to re-install the child seat using the load leg. When each installation is completed, the participant will be led away from the vehicle while a researcher evaluates their work. A researcher who is a CPST will use a data collection form to keep track of all installation errors committed by the participants. The primary outcomes of interest are the rate of load leg installation (without being prompted to use this feature) and correct installation of the load leg. Other errors of interest include routing of the seat belt or lower anchor straps, looseness of attachment, recline angle, etc. A handheld tension gauge will be used to quantify installation tightness. All other metrics are a visual pass/fail metric.

Following the installations, participants will complete a short survey with open-ended queries to describe facilitators or barriers they experienced while installing the seat, as well as what they liked or did not like about the seat. They will use a Likert scale to rate their self-efficacy in installing the seats, if they believed they were installed correctly, and general ease-of-use. Socio-demographic data will also be collected (e.g. gender, age, and socioeconomic status). After study procedures are completed, the researcher will demonstrate how to correctly install the seat and provide the participant with educational materials.

Internal/external validity

Product usability studies are an effective, low-risk way to obtain information about a product design. Published work exists as a model for product usability protocols (for example: Mirman et al. 2015, Mansfield et al. 2018). Product usability studies help to highlight consumer habits and attitudes which engineers and product designers may not be aware of.

Data/statistical analysis

The percentage of participants who install with the load leg (without being prompted) will be recorded. Any installation errors associated with the load leg will also be recorded. Other errors will also be recorded as a percentage of the study sample (belt routing, looseness of attachment, etc.). The rates of these common errors will be compared to those reported in recent literature. There are currently no resources reporting typical error rates for load legs since this feature is not widely available in the current car seat market. The proposed study will provide a benchmark for this factor. Any installation errors with respect to the load leg will be analyzed for their likelihood of causing potential harm to the occupant.

The participant information collected in the surveys will be analyzed using descriptive and inferential statistics. Descriptive statistics such as means, standard deviations, medians, ranges, and frequency distributions will be calculated from the Likert scale data according to type of safety seat. Continuous data will be checked for normality. We will use either paired t-tests or Wilcoxon signed-rank test for correlated data to test the hypothesis of no change on ratings of ease-of-use and self-efficacy. Logistic regression will be used to predict correct load leg usage (pass/fail) using perceived self-efficacy, gender, and age of participants for each device.

Bibliography

Mansfield JA, Zaragoza-Rivera YN, Bolte JB IV. Usability of non-standard lower anchor configurations for child restraint system (CRS) installation. *Traffic Injury Prevention*. [*Accepted 21 Oct 2018, release pending editor's formatting*]

Mirman JH, Seifert SJ, Zonfrillo MR, Metzger K, Durbin DR, Arbogast KB. Evaluating the effect of a mechanical adjunct to improve the installation of child restraint systems to vehicles. *Traffic Injury Prevention*. 2015; 16(sup2):S24-S31.