

**Title:** Tiny Cargo, Big Deal! Pilot trial of an Emergency Department-based intervention to promote child passenger safety best practices

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**Conflicts of Interest:**

MM reports no conflicts of interest relevant to the content of the manuscript.

DK reports no conflicts of interest relevant to the content of the manuscript.

KR reports no conflicts of interest relevant to the content of the manuscript.

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TCBD Tweet

Pilot trial by @MichLMacy @StrohCunningham and co-authors shows promise for ED-based intervention to promote child passenger safety #TheRightSeat

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## ABSTRACT

**Background:** Despite demonstrated effectiveness of child restraint systems (CRSs), use remains suboptimal. In this randomized pilot trial, we sought to determine the feasibility, acceptability, and potential efficacy of “Tiny Cargo, Big Deal” an ED-based intervention to promote guideline concordant size-appropriate CRS use.

**Methods:** Parents of children <11 years old were recruited in two EDs and randomized in a 2x2 factorial design to four conditions: 1) generic information sheet, 2) tailored brochure mailed after the ED visit, 3) a single motivational interviewing-based counseling session in the ED, 4) full intervention (counseling session plus tailored brochure). We assessed feasibility (recruitment, completion, follow-up rates) and acceptability (parent attitudes, uptake of information) in the ED, at 1 month, and at 6 months. We obtained preliminary estimates of effect sizes of the intervention components on appropriate CRS use at 6-month follow-up.

**Results:** Of the 514 parents assessed for eligibility, 456 met inclusion criteria and 347 consented to participate. Enrolled parents were mostly mothers (88.1%), 48.7% were 18 to 29-years-old, 52.5% were non-Hispanic, white, and 65.2% reported size-appropriate CRS use. Completion rates were 97.7% for baseline survey, 81.6% for counseling, 51.9% for 1-month and 59.3% for 6-month follow-up. In the ED, 70.5% rated thinking about child passenger safety in the ED as very helpful. At 1 month, 70.0% expressed positive attitudes toward the study. Of 132 parents who reported receiving study mailings, 78.9% reviewed the information. Parents randomized to the full intervention demonstrated an increase (+6.12 percentage points) and other groups a decrease (-1.69 to -9.3 percentage points) in the proportion of children reported to use a size-appropriate CRS at 6-month follow-up.

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**Conclusions:** Suboptimal CRS use can be identified and intervened upon during a child’s ED visit. A combined approach with ED-based counseling and mailed tailored brochures shows promise to improve size-appropriate CRS use.

## INTRODUCTION

In 2011, the American Academy of Pediatrics (AAP)<sup>1,2</sup> and the National Highway Traffic Safety Administration (NHTSA)<sup>3</sup> updated their child passenger safety recommendations based on a growing body of evidence showing the effectiveness of age and size-appropriate child restraint systems (CRSs) (i.e., car seats and booster seats).<sup>4-6</sup> Since then, little progress has been made in the use of recommended CRSs<sup>7-10</sup> and motor vehicle collisions (MVCs) remain a leading cause of unintentional injury-related deaths for children in the United States (U.S.).<sup>11,12</sup> Many U.S. children travel completely unrestrained<sup>13-15</sup> and differences in CRS use between minority and white children<sup>16,17</sup> contribute to disparities in crash-related fatalities.<sup>18</sup> Additionally, non-fatal injuries place a substantial burden on children, their families, and society.<sup>19-21</sup>

Given these patterns, effective interventions to promote use of appropriate CRSs and address disparities are needed. The emergency department (ED) is a promising setting for injury prevention efforts.<sup>22,23</sup> Prior studies, focused on traditional age categories <4 years for car seats and 4-7 years for booster seats,<sup>24-29</sup> have demonstrated that education can increase parental knowledge but results for behavior change have been mixed.<sup>24,25,29-34</sup>

In this randomized pilot study, we sought to determine the feasibility, acceptability, and the potential efficacy of a novel ED-based counseling session and tailored brochures to promote appropriate CRS use among parents of children <11 years old. We addressed the following

62 objectives to inform the design of a future fully-powered randomized controlled trial (RCT): 1)  
63 to assess feasibility in terms of recruitment, completion of ED-based study interactions,  
64 counseling session fidelity, receipt of mailings, and follow-up; 2) to evaluate the acceptability to  
65 parents of intervention during their child's ED visit and their uptake of information; 3) to  
66 determine if remote data collection with digital photographs is possible; and 4) to obtain  
67 preliminary effect size estimates.

## 68 **MATERIALS AND METHODS**

### 69 **Study Design**

70 We conducted a pilot trial of the intervention described below. Subjects were recruited  
71 6/9/2015-9/29/2015 in two Michigan EDs and randomized to one of four treatment conditions of  
72 increasing intensity in a 2x2 factorial design: 1) enhanced usual care (EUC) - generic  
73 information sheets; 2) generic information sheet plus tailored brochure(s); 3) single motivational  
74 interviewing (MI)-based counseling session plus generic information sheets; 4) full intervention -  
75 single MI-based counseling session plus generic information sheets and tailored brochure(s).  
76 Counseling sessions were conducted in the ED after a baseline survey. Generic information  
77 sheets were distributed in the ED. Tailored brochures were mailed in the following week.  
78 Measures were assessed at ED discharge, one month, and six months. One and 6-month follow-  
79 up assessments were completed by research assistants (RAs), blinded to randomization group,  
80 who entered responses to scripted questions into a survey on the Qualtrics platform (Qualtrics,  
81 LLC, Provo, UT). The Institutional Review Boards of the University of Michigan Medical  
82 School and Hurley Medical Center (HMC) approved this study. The study was registered on  
83 ClinicalTrials.gov (NCT02496481).

### 84 **Setting**

85 Parents were recruited during their child's ED visit at: 1) the Michigan Medicine (MM)  
86 C.S. Mott Children's Hospital or 2) the Hurley Medical Center (HMC). The MM Pediatric ED is  
87 located in a suburban tertiary care, academic hospital with a predominantly white and privately  
88 insured patient population. The HMC general ED is located within an urban community hospital  
89 where higher proportions of patients are African-American and covered by Medicaid compared  
90 with MM. The Hispanic populations at both sites are <5%.

### 91 **Subjects**

92 The potentially eligible study population included adult parents (parents, step-parents,  
93 grandparents, and guardians) of children <11 years' old receiving ED care for any reason during  
94 shifts staffed by RAs. Parents were systematically approached based on order of arrival. Parents  
95 were not approached if their child was critically ill or injured (e.g., Triage Category 1, care in the  
96 resuscitation bay), was flagged as admitted or discharged when the RA screened the tracking  
97 board, or was being evaluated for suspected child abuse. Parents were excluded if they were <18  
98 years old, did not understand/speak English, or if the caregiver did not regularly travel in a car  
99 with the child. RAs measured the child's height and excluded parents of children  $\geq 57$ " tall, the  
100 height at which proper seat belt fit can be achieved without a CRS.<sup>1,35,36</sup>

### 101 **Recruitment and Randomization**

102 RA shifts were scheduled between 10am and 11pm. Recruitment days were varied to  
103 ensure weekday and weekend enrollment. RAs used a standard script to approach parents after  
104 the child was in their treatment room. We tracked patients who were not approached. Written  
105 informed consent was obtained after the RA reviewed study procedures. Parents who enrolled in  
106 the study self-administered an online survey on study tablets (iPad Air, Apple Inc., Cupertino,  
107 CA) using Qualtrics. Parents were randomized by the survey software to one of four treatment  
108 conditions. The survey prompted parents to hand the tablet back to the RA if they were  
109 randomized to receive counseling.

110 Our recruitment target (n=175 participants from each ED) was based on available  
111 resources. We set a goal of retaining 80% at 6-month follow-up (70 per condition). As this was a  
112 pilot trial, we did not conduct a priori power calculations.

### 113 **Incentives**

114 Parents received a \$15 gift card for the ED portion of the study and a \$30 gift card for in  
115 person or a \$10 gift card for telephone interview at 6 months.

### 116 **Enhanced Usual Care**

117 After completing the ED portion of the study, every participant, regardless of  
118 randomization group, received a single-page generic information sheet that summarized  
119 Michigan's child passenger safety law and listed child passenger safety websites and telephone  
120 numbers for local resources. All counseling was provided before the information sheet was given  
121 and no counseling was provided when providing the information sheet. Parents who were

122 randomized to receive generic information sheets were mailed a single page NHTSA flyer  
123 presenting 2011 child passenger safety recommendations by age group.

#### 124 **Tiny Cargo, Big Deal Intervention**

125 Self-Determination Theory<sup>37,38</sup> provided the theoretical basis for the intervention  
126 components: 1) a single brief MI-based counseling session and 2) tailored brochure(s).

##### 127 MI-Based Counseling Session

128 Counseling occurred during the child's ED visit with the goal of motivating consistent use of an  
129 appropriate CRS while providing parents with knowledge and education on child passenger  
130 safety topics of interest. RAs had prior training in MI techniques including supporting autonomy,  
131 reflecting emotion, eliciting change talk, and rolling with resistance. RAs completed a half day  
132 study-specific training on the counseling session and CRSs. RAs guided parents through the  
133 session using prompts on the tablet. The session began with an exercise to draw connections  
134 between parent-identified values and child safety. Importance and confidence rulers were  
135 utilized. The RA explored why and how the parent selected their child's usual restraint and  
136 challenges with CRS use. The RA presented age group-specific social norms for guideline-  
137 adherent CRS use and asked parents how this information relates to them. RAs elicited change  
138 talk when working to align behaviors with recommendations. Parents were provided an  
139 opportunity to set a learning agenda by selecting up to three CRS topics from a pick-list. The  
140 session closed with a summary. Tailored Brochures

141 Families were mailed demographically tailored brochure(s) relevant to their child's usual  
142 CRS and the appropriate CRS if different from the usual in the week following the ED visit. We  
143 developed four tri-fold brochures addressing appropriate CRS transitions and a "Back Seat  
144 Pocket Guide" with a weight-based overview of recommendations. Our messages were crafted to  
145 align with guidance for effective child passenger safety education.<sup>40</sup> Brochures were tailored on  
146 demographic characteristics including child name, age, and size during the ED visit. We used the  
147 child's weight/height growth percentiles from the ED visit to project the age at which the child  
148 would need to transition to the next CRS based on typical CRS size limits. The brochures  
149 contained information about proper fit and referred parents to their child's CRS instructions to  
150 ensure correct installation and use.

#### 151 **Measures**

152 Child Passenger Safety Behaviors

153 Child passenger safety behaviors were assessed at baseline and 6 months with a series of  
154 questions adapted from our prior work.<sup>17</sup> Before randomization, parents were asked about the  
155 child's frequency of motor vehicle travel and use of restraints. If the parent reported using a  
156 restraint, they were asked to indicate which type was used on most trips in the past six months.  
157 Parents who indicated their child did not use any restraint were asked to confirm that response  
158 prior to continuing on with the survey. Parents also were asked where their child usually sits in  
159 the car and how often the child sat in the front seat in the past 6-months. Our previous research  
160 demonstrated substantial agreement (82.6%,  $\kappa = 0.74$ ) between parent-reported CRS and the  
161 observed CRS at ED discharge.<sup>17</sup>

#### 162 Parent and Child Characteristics

163 Demographic characteristics including parent age, gender, relationship to child,  
164 race/ethnic background, highest education level attained, and annual household income in strata  
165 were obtained. Child age, gender, and weight were obtained from the ED record. Child height  
166 was measured by the study RA. For children present at 6-month follow-up, weight and height  
167 were re-measured.

#### 168 Feasibility of Enrollment, Intervention, and Follow-up

169 To assess feasibility, we tracked rates of recruitment, completion of baseline assessments  
170 and counseling sessions, receipt of mailings, and 6-month follow-up.

#### 171 Counseling Session Fidelity

172 Counseling sessions were audio-recorded with the permission of the parent. Trained RAs  
173 rated the counseling sessions utilizing the OnePass coding system.<sup>39</sup> Scores range from 1 to 7  
174 with higher scores indicating greater competence. Counseling sessions with complete and  
175 audible recordings were scored. A 10% sample of the audio-recordings was double coded and  
176 checked for inter-rater reliability. There were significant differences in total points assigned to  
177 the first 7 recordings (range -9 to +8). The team met and discussed coding. Reliability was  
178 achieved with the next 7 recordings (range of differences in total points -3 to +5). The remaining  
179 audio-recordings were coded by two RAs independently.

#### 180 Acceptability

181 In an immediate post-intervention survey, all parents were asked to rate how helpful it  
182 was to think about child passenger safety while in the ED on a scale of 1 (not at all) to 10 (very).  
183 At 1-month follow-up, we gauged parental attitudes by asking "How did you feel about being



184 asked about car seats in the ED?” and probing for specific likes and dislikes. Responses were  
185 transcribed by the RA. At 6-month follow-up, we explored preferred modalities for receiving car  
186 safety information in relation to their child’s ED visit using fixed choice options: 1) in the ED  
187 during the child’s visit, 2) in person a few days after being in the ED, 3) by phone a few days  
188 after being in the ED, 4) in the ED and again a few days later in person, 5) in the ED and again a  
189 few days later by phone. Parents were also asked to indicate their level of interest on a 5-point  
190 scale (1 = not at all; 5= a lot) in three other modalities to promote child passenger safety: 1)  
191 prompts to help them remember to buckle their child up, 2) text messages with information about  
192 keeping their child safer in the car, and 3) an online tool to help them know which seat is right  
193 for their child. We assessed acceptability immediately after the ED portion of the study, by  
194 telephone 1-month after the ED visit, and in-person or by telephone approximately 6-months  
195 after the ED visit.

#### 196 Information Uptake

197 At the conclusion of study interaction in the ED, all parents were asked to rate how likely  
198 they will be to talk about car safety with family and friends on a scale of 1 (not at all) to 10  
199 (very). At 1-month follow-up, we assessed parent-reported receipt of mailings. Parents who  
200 received the mailing were asked if they reviewed the information, and if so, how much of the  
201 information they read (none to all on a 10-point scale). We also asked if they looked at the  
202 information a second time. Information uptake was assessed in the ED and at one month.

#### 203 Outcome Measure: Appropriate CRS Use

204 We determined age- and size-appropriateness of the parent-reported CRS in use at 6-  
205 month follow-up based on a combination of the 2011 recommendations from AAP and NHTSA,  
206 Michigan law, and typical weight limits for CRS (Table 1).<sup>2,41</sup> When possible, parent-reported  
207 CRS type at 6 months was verified by direct in-vehicle observation of the restraint (n=93) or  
208 assessment of the restraint pictured in a digital photograph (n=16) taken by the parent and  
209 submitted via the study email/web link. RAs used a standard checklist for these observations and  
210 recorded information about the type of restraint. For children who were not present at 6-month  
211 follow-up, we estimated growth based on the assumption that a typical 2 to 10-year-old child  
212 gains 3 pounds over 6 months.<sup>42</sup> Although infants experience more rapid growth, there were only  
213 7 children <2 years with missing follow-up weights and only one child’s restraint was changed  
214 from recruitment to follow-up. That child was moved prematurely to a booster seat (baseline

215 weight 27.5 pounds, minimum booster seat weight 40 pounds). We assessed the outcome of  
216 appropriate CRS use at 6-months.

217 We initially planned for all 6-month follow-up assessments to occur in person. In  
218 preparing to schedule 6-month follow-up appointments, we found 67 of 172 families recruited at  
219 MM and 14 of 176 families recruited at HMC lived >15 miles from a follow-up location. To  
220 reduce the burden of travel for follow-up on families, we offered a telephone follow-up option to  
221 those families living >15 miles from a follow-up location. Parents were contacted by telephone,  
222 text, mail, and email to schedule their 6-month follow-up. We invited 32 parents, without  
223 additional incentives, to submit digital photographs to pilot test this approach to supplement self-  
224 reported CRS use.

### 225 **Analyses**

226 Descriptive statistics were calculated. We set feasibility targets of 80% for recruitment,  
227 survey and counseling session completion, receipt of mailings, and 6-month follow-up. MI-  
228 session fidelity was assessed by calculating the average score on the OnePass for each  
229 counseling session with an audible recording. A counselor who scores an average 5 of 7 points is  
230 considered competent in MI.<sup>39</sup> Chi-square tests were used to compare acceptability of the  
231 intervention and uptake across treatment groups and for minority compared with non-Hispanic,  
232 white parents. For analyses, we set a threshold of 8 or more on the 10 point scale as indicative of  
233 a high level of helpfulness or likelihood to share information. We considered selection of  
234 anything other than “not at all” as having at least some interest in the alternative modalities to  
235 promote child passenger safety. We examined the amount of mailed information that the parent  
236 reviewed in three categories: 1) half or less, 2) more than half but not all, or 3) all. We did not  
237 have a priori targets for acceptability or uptake. We present results in terms of proportions with  
238 95% confidence intervals (CI). The kappa statistic was used to assess the agreement between  
239 reported and observed CRS at six-month follow-up when observations were available, with a  
240 goal of at least substantial agreement (kappa of greater than 0.61).<sup>43</sup>

241 Responses to the 1-month follow-up question “How did you feel about being asked about  
242 car seats in the ED?” were coded as positive, negative, or neutral by a study investigator (MLM)  
243 blinded to randomization group using the text analysis tool within Qualtrics. Comments that used  
244 terms such as good, happy, pleasant, nice, helpful were considered positive; fine and ok were

245 considered neutral; stressful, inconvenient, hard were considered negative. Coding was then  
246 reviewed by a study RA and discrepancies were resolved with discussion.

247 Intention to treat analyses were used for the preliminary outcome assessment. We  
248 calculated differences in proportions with 95% confidence intervals (CI) for changes in  
249 appropriate CRS from baseline to 6-month follow-up for the four intervention groups. We  
250 conducted a multiple variable analysis of the intervention components in a logistic regression  
251 model of appropriate restraint use at six months. We explored socioeconomic co-variables that  
252 influence child passenger safety behaviors based on prior literature. We retained variables with  
253  $p \leq 0.20$  in bivariate analyses. We completed planned stratified analyses by child age category (<2  
254 years, 2-4 years, 5-10 years) and use of an appropriate CRS at baseline. We hypothesized that the  
255 type of restraint recommended for each age group and the use of the appropriate CRS at baseline  
256 may influence the response to the intervention, however there was insufficient sample size to  
257 formally test for these possible interaction effects. Analyses were conducted using Stata 13.1  
258 (StataCorp, College Station, TX).

## 259 **RESULTS:**

260 Subject flow is presented in Figure 1. There were 514 parents assessed for eligibility. Of  
261 the 456 who met inclusion criteria, 76.0% consented. Parents who consented were similar to  
262 those who declined in terms of study site, child age, triage level, and ED length of stay prior to  
263 being approached (results not shown). Recruitment was evenly divided between sites. Baseline  
264 assessments were completed by 339 parents who enrolled (97.7%). Most parents were mothers  
265 (88.1%), 48.7% of parents were 18 to 29-years-old, and 52.5% of parents were non-Hispanic,  
266 white. At baseline, for the full sample, independent of treatment arm, 65.2% (95% CI: 59.9,  
267 70.1) of parents reported in the past 6 months their child usually used a CRS that was considered  
268 to be appropriate by our study definition, 86.8% (95% CI: 82.7, 90.1) reported their child never  
269 traveled unrestrained, and 89.6% (95% CI: 85.9, 92.5) reported their child always sat in the back  
270 seat. Baseline parent and child characteristics were similar across intervention arms with the  
271 exception of annual family income, which was lower among parents randomized to the full  
272 intervention (Table 2).

### 273 Counseling Session Feasibility and Fidelity

274 Of the 163 parents randomized to receive counseling, 133 (82.6%, 95%CI: 75.9, 87.7)  
275 completed the session. The main reason for non-completion was because the child was

276 discharged during the study interaction. The survey was not programmed with a hard-stop after  
277 the baseline assessment and four parents did not hand the tablet back to the RA when the survey  
278 prompted them to do so. These parents went through the counseling session screens without  
279 interacting with the RA. Counseling sessions were on average 13 minutes in duration (standard  
280 deviation (sd) 4.9). For the 135 counseling sessions with audible recordings, the mean OnePass  
281 Score was 5.0 (sd 0.69) on the 7-point scale, indicating the counselors were skilled.

## 282 Follow-up Feasibility

283 We reached 180 parents by telephone at one month (51.9%; 95% CI: 46.6, 57.2). The  
284 ability to reach families was similar across treatment groups and between study sites. Of the  
285 families who could not be reached, there were 17 wrong numbers, 26 numbers were no longer in  
286 service, and 12 numbers were not accepting calls. Seventy-five percent of parents reported  
287 receiving the study mailings, without differences between those randomized to tailored (76.5%;  
288 95% CI: 66.2, 84.3) vs. generic information (75.8%; 95% CI: 65.9, 83.6). Only 6 mailings were  
289 returned by the postal service (3 tailored and 3 generic information).

290 Six-month follow-up was completed by 201 parents (59.3%; 95% CI: 54.0, 64.4) and 55.2%  
291 (95% CI: 48.3, 62.0) of follow-up appointments were conducted in person. Parents who  
292 completed 6-month follow-up were similar to those who did not in terms of randomization group  
293 and baseline behaviors (appropriate restraint use: 65.7%; 95% CI: 58.8, 71.9 vs. 64.5%; 95% CI:  
294 56.1, 72.0; never traveled unrestrained: 88.5%; 95% CI: 83.3, 92.2 vs. 84.3%; 95% CI: 77.1,  
295 89.6) but were more likely to have been recruited at MM and to have attained higher education  
296 levels (Table 2). We attained higher rates of in-person follow-up at HMC (59.6%; 95% CI: 49.0,  
297 69.3) than MM (51.8%; 95% CI: 42.5, 60.9). Acceptability

298 Measures of acceptability are presented in Table 3. In the immediate post-intervention  
299 survey, overall 70.5% (95% CI: 65.3, 75.2) of parents rated thinking about child passenger safety  
300 in the ED as very helpful (8 or more on a 10 point scale), with slightly higher proportions of  
301 parents who received an MI session giving a rating of 8 or higher. At 1-month follow-up, 70.0%  
302 (95% CI: 62.9, 76.5) of parents provided open-ended comments indicating positive attitudes  
303 toward the study interaction in the ED, 27.0% (95% CI: 20.9, 34.1) were neutral, and 2.9% (95%  
304 CI: 1.2, 6.8) were negative. Responses were similar for those who were randomized to receive an  
305 ED-MI session and those who were not. When asked specifically about dislikes, eleven parents  
306 shared an example, most commonly that the interaction took too long or the timing was bad.

307 Higher proportions of minority parents rated the information as very helpful (81.0%; 95% CI:  
308 74.0, 86.5) vs. non-Hispanic, white (61.0%; 95% CI: 53.5,68.1) and expressed neutral feelings  
309 about the ED intervention (35.6%; 95% CI: 25.4, 47.3) vs. non-Hispanic, white (20.8%; 95% CI:  
310 13.9, 29.9). At 6-month follow-up, parents had varied preferences for receiving information about  
311 child passenger safety but more than half of parents selected an option that included the ED visit.  
312 Preferences did not differ significantly by treatment group. Few parents completing 6-month  
313 follow-up had at least some interest in prompts to remind them to buckle their child up (12.1%;  
314 95% CI: 8.2, 17.6). More parents indicated at least some interest in receiving informational texts  
315 about child passenger safety (40.8%; 95% CI: 34.1, 48.0%). Most parents indicated some interest  
316 in an online tool that would help them know what safety seat is right for their child (74.9%; 95%  
317 CI: 68.2, 80.5). Comparisons by intervention group are shown in Table 3. Minority parents were  
318 more interested in prompts but equally interested in texts and online tools as non-Hispanic, white  
319 parents (results not shown).

#### 320 Information Uptake

321 In the immediate post-intervention survey, higher proportions of parents randomized to  
322 counseling reported they were very likely to share the information with family (71.1%; 95% CI:  
323 63.3, 77.7) and friends (68.8% (95% CI: 61.0, 75.8) compared with parents who were not  
324 (60.3%; 95% CI: 52.9, 67.4 for family and 56.3%; 95% CI: 48.8, 63.5 for friends). Most of the  
325 132 parents who received the study mailing reported reviewing the information (78.0%; 95% CI:  
326 70.1, 84.3). A slightly higher proportion of parents who received tailored brochures reported  
327 reviewing the information (82.5%; 95% CI: 71.0, 90.1) compared with those who received  
328 generic information (73.9%; 95% CI: 62.2, 83.0). Of parents who reviewed the mailings, 29.1%  
329 (95% CI: 21.1, 38.7) indicated they read half of the information or less, 28.2% (95% CI: 20.2,  
330 37.7) read more than half but not all of the information, 42.7% (95% CI: 33.4, 52.5) read all of  
331 the information, and 35.3% (95% CI: 26.6, 45.1) referred back to the information a second time.  
332 Results were similar for parents who received tailored brochures and generic information sheets.  
333 Higher proportions of minority parents indicated they would be very likely to share information  
334 with family [72.9% (95% CI: 65.3, 79.3) vs. 58.5% (95% CI: 50.9, 65.7) non-Hispanic, white]  
335 and friends [68.8% (95% CI: 61.1, 75.7) vs. 56.1% (95% CI: 48.6, 63.4) non-Hispanic white].  
336 Although fewer minority parents reviewed the mailed information [71.2% (95% CI: 57.4, 81.9)  
337 vs. 82.5% (72.5, 89.4) non-Hispanic, white], more minority parents referred back to the

338 information if they had read it [51.3% (95% CI: 35.5, 67.0) vs. 26.1% (16.9, 38.3) non-Hispanic,  
339 white].

#### 340 Preliminary Effect-Size Estimates

341 At 6-month follow-up, 62.7% (95% CI: 55.8, 69.1) of parents reported that in the past 6  
342 months their child usually used a CRS considered appropriate, 86.1% (95% CI: 80.5, 90.2)  
343 reported their child never traveled unrestrained, and 88.1% (95% CI: 82.8, 91.9) reported their  
344 child always sat in the back seat. Parent-reported CRS was verified with in-vehicle observation  
345 for 109 families (93 in-person and 16 photographs). CRS appropriateness did not differ by  
346 method [64.0% (95% CI: 54.6, 72.4) in-person vs. 61.1% (95% CI: 50.6, 70.6) photograph].  
347 Agreement between reported and observed CRS was 92.6% (kappa 0.90,  $p < 0.001$ ) overall,  
348 91.4% for in-person (kappa 0.88,  $p < 0.001$ ) and 100% for photograph (kappa 1,  $p < 0.001$ ).

349 Parents randomized to receive the full intervention demonstrated an increase (+6.1  
350 percentage points) and other groups a decrease (-1.7 to -9.3 percentage points) in the proportion  
351 of children reported to use a CRS considered appropriate at 6-month follow-up, although  
352 differences were not statistically significant (Figure 2). Table 4 shows results stratified by child  
353 age group and restraint appropriateness at baseline. Overall, parents of children  $< 2$  years showed  
354 decreased appropriate restraint use at 6 months, with smaller decreases among those randomized  
355 to the full intervention or EUC. Parents of 2 to 4 and 5 to 10-year-olds randomized to the full  
356 intervention had greater increases in appropriate CRS use than other groups. Among parents of  
357 children who were using an appropriate CRS at baseline, the smallest decrease in appropriate  
358 CRS use was observed for those randomized to the full intervention. Among children who were  
359 not using an appropriate CRS at baseline, the greatest increase in appropriate restraint use was  
360 observed for those randomized to receive tailored brochure(s).

361 The unadjusted odds ratio of appropriate CRS use at 6-months was 1.45 (95% CI: 0.65,  
362 3.23) for the full intervention vs. EUC, 0.98 (95% CI: 0.44, 2.18) for the tailored brochure(s) vs.  
363 EUC, and 0.96 (95% CI: 0.44, 2.07) for counseling vs. EUC. Among parents who reported using  
364 an appropriate CRS at baseline, unadjusted odds of appropriate restraint use at 6 months was  
365 3.38 (95% CI: 0.65, 17.66) for the full intervention vs. EUC, 0.54 (0.18, 1.69) for the tailored  
366 brochure vs. EUC, and 0.76 (95% CI: 0.24, 2.38) for counseling vs. EUC. Among children  
367 reported to not be using an appropriate CRS at baseline, the unadjusted odds of appropriate  
368 restraint use at 6 months was 1.02 (95% CI: 0.25, 4.14) for the full intervention vs. EUC, 1.67

369 (0.39, 7.17) for the tailored brochure vs. EUC, and 0.89 (95% CI: 0.20, 3.67) for counseling vs.  
370 EUC. Similar patterns were observed in the adjusted analyses (Table 5).

## 371 **DISCUSSION**

372 In this two site, randomized pilot trial we demonstrated that the ED-based Tiny Cargo,  
373 Big Deal child passenger safety intervention was feasible and acceptable across our diverse  
374 sample of parents. Almost half of study parents reported using a CRS that was not considered  
375 appropriate and about 10% had allowed their child to travel unrestrained or sit in the front seat.  
376 Minority parents found talking about child passenger safety in the ED to be more helpful and  
377 they were more likely to plan to share information learned with family and friends than non-  
378 Hispanic, white parents. These findings support our assertion that suboptimal child passenger  
379 safety behaviors can be identified in the ED and the ED may be an opportune setting to address  
380 disparities. We also demonstrated that digital photographs can be used to remotely assess CRS  
381 use and verify parent self-report without the burden of in-person follow-up.

382 This study allowed us to learn several important lessons for improvement prior to a full-  
383 scale RCT. Our MI-based counseling session was acceptable to and completed by the majority of  
384 parents. We anticipate completion rates can be increased by engaging with parents earlier in their  
385 child's ED visit. Parents who received tailored brochures were more likely to review  
386 information. This signals that even minimal demographic tailoring increases uptake. In addition,  
387 participants were interested in online tools for child passenger safety. Prior to a planned RCT, we  
388 will convert the print materials into an online resource with deeper tailoring on psychosocial  
389 variables and knowledge. Many parents who completed 6-month follow-up indicated interest in  
390 receiving additional information after discharge. A telephone counseling session in the days after  
391 ED discharge may be a useful addition. These modifications may strengthen the impact of the  
392 intervention on appropriate CRS use.

393 We found evidence for the potential additive benefit of the intervention components on  
394 appropriate CRS use at 6 months, particularly among parents who were using an appropriate  
395 restraint at baseline. The full intervention may encourage parents to delay the transition out of an  
396 appropriate restraint. This hypothesis could be tested by studying parents who plan to make a  
397 premature transition in the months following enrollment. The tailored brochure was associated  
398 with increased appropriate restraint use among children who were not using an appropriate

399 restraint at baseline. Future research targeting parents who are not guideline adherent at baseline  
400 may be higher yield than intervening with parents who plan to continue appropriate CRS use.

401 The lack of intervention effect among parents of children <2 may be due to limited  
402 acceptance of newer guidance to keep U.S. children rear-facing until at least 2 years of age. The  
403 AAP has recently reaffirmed their position on rear-facing car seat use<sup>49</sup> and several states have  
404 passed legislation mandating rear-facing until age 2.<sup>50</sup> Policy changes specific to rear-facing car  
405 seat use for toddlers can be incorporated to make the intervention more influential on parent  
406 decision-making about when to turn their child from a rear to forward-facing car seat.

#### 407 **Limitations:**

408 This pilot study has several limitations. First, there are several factors that decreased our  
409 chances of detecting an intervention effect. The lack of a true control condition (all parents  
410 received some educational materials) decreases the potential for differences in the outcome  
411 between conditions. It is also possible that the intervention dose was too low to show an effect or  
412 that the individual intervention components led parents to different conclusions about the  
413 appropriate CRS. Second, we were able to retain just over half of enrolled parents. Our results  
414 may be biased toward parents who were more willing and able to complete follow-up and  
415 possibly parents who were more interested in child passenger safety. The EUC group had the  
416 highest 6-month follow-up rates. Third, our results may not be generalizable to settings with  
417 robust public transportation systems or to non-English speaking populations. Fourth, there is  
418 potential for social desirability bias. We estimate these effects are minimal as many parents  
419 reported socially undesirable behaviors including allowing their child to travel unrestrained. We  
420 also found high agreement between the parent-reported and observed CRS. Lastly, recruitment of  
421 parents from June through September and during daytime and evening hours may introduce  
422 sampling bias but we cannot estimate the direction of this effect.

423

424 In conclusion, suboptimal child passenger safety behaviors can be identified and intervened upon  
425 during a child's ED visit. An MI-based counseling session in the ED combined with mailed  
426 tailored brochures resulted in raw improvements in appropriate CRS use among parents of  
427 children <11 years old compared with enhanced usual care.

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558 **Figure 1 Legend:** Consort flow diagram of study recruitment and participation.

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564 **Figure 2 Legend:** Percent of children reported to be using a restraint that was considered to be  
565 age and size-appropriate at baseline (gray bars) and 6-month follow-up (black bars) by  
566 intervention group.

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Table 1: Age- and Size-Appropriate Child Passenger Restraints

Weight	10	20	30	40	50	60	70	80	90
Age Group									
<b>&lt;2 years</b>									
<b>2-4 years</b>									
<b>5-10 years</b>									

\*The weight ranges for children in the sample by age category were as follows: <2 year olds, 5 to 32 pounds; 2-4 year olds 21.5 to 78.5; 5-10 year olds 38 to 163. Child weight at follow-up was estimated (using baseline weight + 3.3 pounds) for 18 of 111 in person follow-up visits and 90 telephone follow-ups. Analysis assuming children did not grow over the 6-month period, 56.2% of CRS would be considered appropriate at follow-up. When we assumed growth, 62.7% of CRS were considered appropriate at follow-up.

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Table 2: Baseline Sample Characteristics and Randomization

	Enhanced usual care n=97	Tailored brochure n=81	ED MI n=81	ED MI + tailored brochure n=80	Overall Sample N=339	Completed 6-month Follow-up n=201
<b>Site</b>						
Hurley Medical Center	50.5	48.2	50.6	50.0	49.9	44.3
Michigan Medicine	49.5	51.8	49.4	50.0	50.1	55.7
<b>Parent Race/Ethnicity</b>						
Minority	50.5	53.1	55.6	52.5	52.8	44.8
Non-Hispanic, white	49.5	46.9	44.4	47.5	47.2	55.2
<b>Parent Age, years</b>						
18-24	26.8	27.2	22.2	21.3	24.5	20.9
25-29	20.6	24.7	24.7	26.3	23.9	21.4
30-39	37.1	34.6	37.0	40.0	37.2	42.3
40-62	14.4	11.1	11.1	7.5	11.2	12.9
Missing	1.0	2.5	4.9	5.0	3.2	2.5
<b>Relationship to Child</b>						
Mother	87.6	87.7	87.7	88.8	87.9	88.1
Father	9.3	9.9	11.1	10.0	10.0	9.9
Grandparent/Other	3.1	2.5	1.2	1.2	2.1	2.0
<b>Highest Education Level</b>						
High school or less	49.5	48.2	51.9	52.5	50.4	41.8
Associates or higher	50.5	51.8	48.1	47.5	49.6	58.2
<b>Annual Household Income</b>						
≤\$25,000	46.4	48.2	55.6	66.2	53.7	43.8
>\$25,000	53.6	51.8	44.4	33.8	46.3	56.2
<b>Child gender</b>						
Male	57.7	48.2	45.0	62.5	53.6	51.7
Female	42.3	51.8	55.0	37.5	46.4	48.3
<b>Child age, years</b>						
<2	38.1	34.6	37.0	28.7	34.8	35.8



2-4	29.9	35.8	38.3	42.5	36.3	34.8
5-10	32.0	29.6	24.7	28.7	28.9	29.3
<b>Usual child passenger restraint system at enrollment</b>						
Rear-facing	28.9	30.9	32.1	20.0	28.0	28.9
Forward-facing	32.0	32.1	34.6	40.0	34.5	34.8
Booster seat	26.8	28.4	24.7	33.8	28.3	27.4
Seat belt	12.4	8.6	8.6	6.2	9.1	9.0
<b>Age and size-appropriate restraint at enrollment</b>						
Yes	67.0	65.4	65.4	62.5	65.2	65.7
No	33.0	34.6	34.6	37.5	34.8	34.3

Abbreviations: ED = emergency department, MI = motivational interviewing

Table 3: Acceptability of the Intervention

	No ED MI	ED MI
<b>At the conclusion of study interaction in ED</b>	<b>n=173</b>	<b>n=152</b>
	% (95% CI)	% (95% CI)
Information was very helpful*	67 (60, 74)	74 (67, 81)
<b>At 1-month follow-up</b>	<b>n=77</b>	<b>n=97</b>
<i>Response to "How did you feel about being asked about</i>		
Positive	71 (61, 79)	69 (58, 78)
Neutral	27 (19, 37)	27 (19, 38)
Negative	2 (0.5, 8)	4 (1, 12)
	Enhanced usual care	Tailored brochure
		ED MI
		ED MI + tailored

				brochure
<b>At 6-month follow-up</b>	<b>n=58</b>	<b>n=42</b>	<b>n=48</b>	<b>n=44</b>
Preference for setting to receive child passenger safety education	% (95% CI)	% (95% CI)	% (95% CI)	% (95% CI)
ED visit only	17 (9, 29)	21 (11, 36)	42 (29, 56)	23 (13, 37)
ED visit and then by phone	40 (28, 53)	29 (17, 44)	27 (16, 41)	32 (20, 47)
ED visit and then in person	10 (5, 21)	17 (8, 31)	0	11 (5, 25)
By phone a few days after ED visit	22 (13, 35)	26 (15, 41)	19 (10, 32)	23 (13, 37)
In person a few days after ED visit	10 (5, 21)	7 (2, 20)	12 (6, 25)	11 (5, 25)
Interest in other methods to improve child passenger safety				
Prompts to help me remember to buckle my child up	19 (11, 32)	10 (4, 23)	13 (6, 26)	5 (1, 17)
Text messages with information about keep my child safer in the car	47 (34, 59)	38 (25, 54)	38 (26, 53)	39 (25, 54)
An online tool to help me know which seat is right for my child	78 (65, 87)	76 (61, 87)	70 (56, 82)	75 (60, 86)

Abbreviations: ED = emergency department, MI = motivational interviewing

\*Rating of  $\geq 8$  on a 10 point scale.

Table 4: Change in Parent-Reported Usual Restraint Considered Age and Size-Appropriate by Intervention Group

	Usual Restraint is Considered Appropriate
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	Baseline	Follow-up	$\Delta$ (95% CI)
<b>Overall (n=201)</b>			
Enhanced usual care	62.7	61.0	-1.7 (-19.2, 15.8)
Tailored brochure(s)	69.8	60.5	-9.3 (-29.3, 10.7)
ED MI + generic information sheet	68.0	60.0	-8.0 (-26.7, 10.7)
ED MI + tailored brochure(s)	63.3	69.4	+6.1 (-12.6, 24.8)
<b>&lt;2 years (n=72)</b>			
Enhanced usual care	72.7	68.2	-4.5 (-37.1, 28.1)
Tailored brochure(s)	86.7	60.0	-26.7 (-52.8, -0.57)
ED MI + generic information sheet	85.0	65.0	-20.0 (-50.1, 10.1)
ED MI + tailored brochure(s)	66.7	53.3	-13.4 (-42.0, 15.3)
<b>2 to 4 years (n=70)</b>			
Enhanced usual care	53.3	46.7	-6.6 (-36.8, 74.6)
Tailored brochure(s)	50.0	62.5	+12.5 (-19.6, 73.1)
ED MI + generic information sheet	55.6	55.5	-0.1 (-34.5, 34.3)
ED MI + tailored brochure(s)	57.1	71.4	+14.3 (-19.6, 48.2)
<b>5 to 10 years (n=59)</b>			
Enhanced usual care	59.1	63.6	+4.5 (-32.9, 41.9)
Tailored brochure(s)	75.0	58.3	-16.7 (-53.8, 20.4)
ED MI + generic information sheet	58.3	58.3	0 (-39.4, 39.4)
ED MI + tailored brochure(s)	69.2	84.6	+15.4 (-9.1, 39.9)
<b>Using an appropriate CRS at baseline (n=132)</b>			
Enhanced usual care	100	81.1	-18.9 (-30.1, -0.06)
Tailored brochure(s)	100	70.0	-30.0 (-46.4, -13.6)
ED MI + generic information sheet	100	76.5	-23.5 (-37.8, -9.25)
ED MI + tailored brochure(s)	100	93.6	-6.4 (-15.0, -2.22)
<b>NOT using an appropriate CRS at baseline (n=69)</b>			
Enhanced usual care	0	27.3	+27.3 (8.7, 45.9)

Tailored brochure(s)	0	38.5	+38.5 (12.0, 64.9)
ED MI + generic information sheet	0	25.0	+25.0 (3.8, 46.2)
ED MI + tailored brochure(s)	0	27.8	+27.9 (7.1, 48.5)

Abbreviations: ED = emergency department, MI = motivational interviewing

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Table 5: Adjusted Odds of Parent Reported Child Passenger Safety Behaviors Considered Guideline Adherent at 6-month Follow-Up Stratified by Child Restraint System Use at Enrollment and Child Age

Study Condition	Full Sample (n=201)				Age and size-appropriate CRS use at enrollment			
	Unadjusted		Adjusted		Yes (n=132)		No (n=69)	
	OR	95% CI	AOR <sup>o</sup>	95% CI	AOR*	95% CI	AOR*	95% CI
Enhanced usual care	Ref	--	Ref	--	Ref	--	Ref	--
Tailored brochure	0.98	0.44, 2.18	0.61	0.23, 1.64	0.65	0.18, 2.31	1.14	0.20, 6.60
ED MI	0.96	0.44, 2.07	0.64	0.23, 1.76	0.81	0.22, 3.05	0.55	0.10, 2.88
ED MI + tailored brochure	1.45	0.65, 3.23	1.13	0.39, 3.24	3.3	0.55, 19.91	0.86	0.18, 4.08

Abbreviations: ED = emergency department, MI = motivational interviewing, OR = odds ratio, AOR = adjusted odds ratio

<sup>o</sup>Adjusted for study site, parent race/ethnicity, family income, size-appropriate restraint use at enrollment, never travelled unrestrained in the 6 months prior to enrollment, always sit in back seat in the 6 months prior to enrollment

\*Stratified by size-appropriate restraint use at enrollment and adjusted for study site, parent race/ethnicity, family income, never travelled unrestrained in the 6 months prior to enrollment, always sit in back seat in the 6 months prior to enrollment.



