1-1-2021

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Received: 28 August 2020 | Revised: 19 November 2020 | Accepted: 8 December 2020 | Published online: 16 February 2021

DOI: 10.1002/trc2.12140

Alzheimer's & Dementia
Translational Research & Clinical Interventions

RESEARCH ARTICLE

Video feedback intervention for cognitively impaired older drivers: A randomized clinical trial

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Funding information
Alzheimer's Association, Grant/Award Number: #NPSASA-15-362133

Abstract

Introduction: This clinical trial aimed to determine whether in-car video feedback about unsafe driving events (UDE) to cognitively impaired older drivers and family members leads to a reduction in such driving behaviors.

Methods: We randomized 51 cognitively impaired older drivers to receive either (1) a weekly progress report with recommendations and access to their videos, or (2) video monitoring alone without feedback over 3 months.

Results: UDE frequency/1000 miles was reduced by 12% in feedback (rate ratio [RR] = 0.88, 95% confidence interval [CI] = .58–1.34), while remaining constant with only monitoring (RR = 1.01, 95% CI = .68–1.51). UDE severity/1000 miles was reduced by 37% in feedback (RR = 0.63, 95% CI = .31–1.27), but increased by 40% in monitoring (RR = 1.40, 95% CI = .68–2.90). Cognitive impairment moderated intervention effects ($P = .03$) on UDE frequency.

Discussion: Results suggest the potential to improve driving safety among mild cognitively impaired older drivers using a behavior modification approach aimed at problem behaviors detected in their natural driving environment.

KEYWORDS
Alzheimer's disease, clinical trial, dementia, driving, mild cognitive impairment

1 | INTRODUCTION

The majority of the research studies and public policies addressing dementia and driving focus on defining methods to detect and retire unsafe drivers.[1–5] Little attention has been paid to interventions to prolong the time that cognitively impaired older drivers can drive safely and maintain their transportation independence.[1,6] While programs using educational and cognitive training in normal elders provide encouraging prospects for enhancing driver safety,[7–18] implementation would be challenging for the cognitively impaired. It appears unlikely these types of interventions would have a lasting benefit for drivers with a progressive neurodegenerative disease such as Alzheimer's disease (AD). A more intensive, individualized behavioral program directly addressing their actual problem driving behaviors, with involvement of family members, has potential to be successful in this group of at-risk drivers. Post-drive feedback using in-car technology holds great promise for the design and implementation of such a program.[19–22]

Our group completed an open feasibility trial in this target population using a naturalistic video intervention aimed at improving specific problem behaviors identified in their driving.[23] These problem behaviors triggered by g-forces were labeled as "unsafe driving events" (UDEs), and included various driving errors, near-crashes, and crashes. Mean total UDEs per 1000 miles were reduced from baseline by 38%

during intervention, and by 59% during post-intervention. Mean total UDE severity scores per 1000 miles were reduced from baseline by 43% during the intervention and by 56% during post-intervention monitoring.

These preliminary results suggested that driving safety among older drivers with cognitive impairment can be improved using a behavior modification approach aimed at problem behaviors detected in their natural driving environment. The effect size was comparable to similar studies in truck[24] and ambulance drivers,[25] but not as high as that reported in teen drivers using DriveCam feedback over a similar time period (57%–83%).[26–28]

The primary aims for this clinical trial were to demonstrate that g-force–triggered video technology can effectively detect UDEs in cognitively impaired older adults and that providing feedback about these events to the drivers and their family members can lead to a reduction in the frequency and severity of unsafe driving behaviors.

RESEARCH IN CONTEXT

1. **Systematic review**: The authors reviewed the literature using traditional sources, meeting abstracts and presentations. Previous publications on older drivers with cognitive impairment or early Alzheimer's disease focus on methods to identify unsafe drivers and remove them from the driving pool rather than interventions to help them drive safely and remain mobile and independent. No study has examined whether a behavioral feedback intervention can help these people drive more safely.
2. **Interpretation**: In this randomized, assessor-blinded, clinical trial of 51 cognitively impaired older drivers, video feedback resulted in reduction of both unsafe driving events and overall severity of unsafe driving events compared to video monitoring alone.
3. **Future directions**: These preliminary results suggest that it is possible to improve the safety of cognitively impaired drivers. Similar feedback interventions could be developed in the future using the rapidly expanding availability of in-car safety technology.

2 | METHODS

The study design consisted of a 3-month baseline period, followed by a 3-month randomized controlled intervention phase (monitoring vs. feedback training), then a 6-month post-intervention phase.

The study is registered in ClinicalTrials.gov as ID: NCT02600026. All participants signed informed consent approved by the Rhode Island Hospital Institutional Review Board.

2.1 | Subjects

Seventy subjects, age > 50 years, from the Rhode Island Hospital Alzheimer's Disease and Memory Disorders Center, a multidisciplinary outpatient memory clinic, expressed interest in the program and were judged eligible according to selection criteria outlined below. Figure 1 shows patient flow figures through all three study phases.

2.2 | Inclusion criteria

All participants underwent a dementia diagnostic evaluation by a neurologist at the Center. Neurological examination results were judged to be normal for age or consistent with AD. Mini-Mental State Examination (MMSE)[29] scores were < 28, Clinical Dementia Rating (CDR)[30] scores were categorized as 0.5 or 1 indicating questionable to mild dementia; all held a valid driving license and ≥ 10 years of driving experience; and had an adult family member or other caregiver, age ≥ 21, to participate in video feedback and CDR interview.

2.3 | Exclusion criteria

Subjects were excluded who had ophthalmologic, physical, or neurologic disorders other than dementia that impair their driving abilities, visual acuity worse than 20/40 in best eye using distance vision measured by wall chart, homonymous hemianopia or bitemporal hemianopia, musculoskeletal disorders causing major physical handicaps, history of alcohol or substance abuse by Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria within the past year, had used sedating medications that impair level of consciousness or attention, had a language impairment that would interfere with the ability to participate in the educational intervention, or had a previous road test evaluation or opinion of caregiver or health professional that they were unsafe to drive.

2.4 | Outcomes

Each g-force–triggered event was analyzed by DriveCam's video assessment staff and assigned a point value based on the characteristics of the event, including severity, fault, driver's actions, safety factors, environmental factors, distraction types, and social factors and people involved, using a standardized rating scale developed by DriveCam for commercial use.[25]

The primary outcome was total number of UDEs (rated by convention as > 5 points), including incidents, near-crashes, and crashes, subclassified as being triggered by hard turns, severe braking, or impact, adjusted for miles driven.

Other clinically important outcomes were collected including (1) the total of severity rating scores for all unsafe events (i.e., sum of all demerit points for events rated > 5) adjusted for miles driven, during intervention and 6-month follow-up, and (2) time to driving cessation (e.g., due to road-test failure, at-fault motor vehicle accident, cognitive decline progression) over 1 year from baseline. The

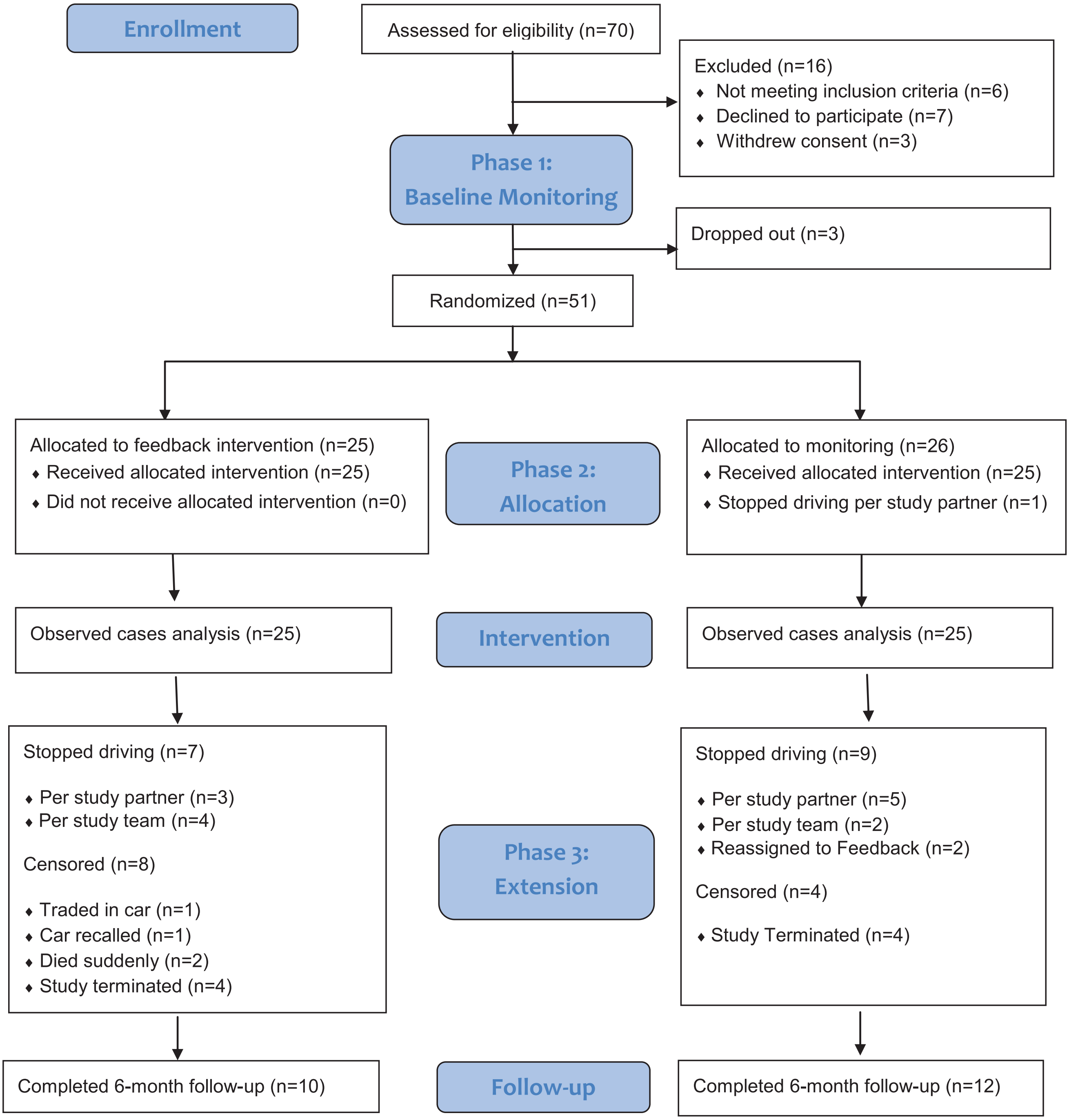

FIGURE 1 Participant flow diagram

severity rating score derived and reported by DriveCam experts has been previously used in a longitudinal study of ambulance drivers[25] demonstrating reduction in not only events, but also severity scores for events, as well as our own feasibility study. The specific events or problems were graded for safety risk on a 0 to 10 demerit scale. A single unsafe driving event could have more than one demerit category, such as judgment error combined with poor awareness of intersection, leading to a combined driving severity rating score for the individual items. Information on time to driving cessation, that is, "driving retirement," was obtained from unscheduled self-reports by family members or a year-end follow-up call to the driving participant and family member.

2.5 | Study procedures

2.5.1 | Baseline office assessment

Subjects completed a Minnesota Cognitive Acuity Screen (MCAS) to measure global cognitive function at baseline and during the course of the study. The MCAS was repeated at 3, 6, and 12 months by telephone to provide information on cognitive decline as a covariate. The MCAS has good reliability and validity in discriminating older adults with normal cognition, mild cognitive impairment (MCI), and dementia, as well as having predictive ability for functional and cognitive decline longitudinally.[31] Study partners completed a log of estimated trips made/week, miles travelled/week, and any accidents during the previous 2 years.

2.5.2 | Baseline driving monitoring (months 0–3)

During baseline, all subjects drove for 3 months with cameras installed and recording events, and no feedback training, unless there was an event felt to be so unsafe as to preclude continued driving. Participants were then urn-randomized to video feedback versus control condition on CDR to ensure that study arms were matched on dementia severity.

2.5.3 | Randomized controlled driving intervention phase (months 4–6)

The intervention phase consisted of two experimental arms: monitoring alone and video feedback. During the intervention phase, those subjects assigned to video feedback received a weekly report and DVD of UDEs. Those subjects assigned to monitoring alone continued driving with the camera activated, but they only received a verbal and written report during the trial if an accident was detected or the research team advised that they cease driving. Otherwise, they received information on their driving performance during the final office visit at 1 year.

2.5.4 | DriveCam

The palm-sized video event recorder was mounted on the windshield behind the rearview mirror with an adhesive. The views were the forward roadway and the driver in the vehicle. Once installed, the camera continuously captured video and temporarily saved the previous several seconds in a video buffer when the vehicle was operating. If the device was not triggered by excessive g-forces, all data was deleted permanently 10 seconds later. Data was protected from unauthorized access and removal and was only viewable by DriveCam's professionals, our research staff, and study participants. The DriveCam reports and videos were reviewed weekly by the investigation site research staff. DriveCam staff were blind to intervention group membership and diagnosis.

2.5.5 | Video feedback intervention

In the video feedback intervention arm, the driver and study partner had weekly access to their driving performance on the DriveCam website as well as through DVDs prepared by study personnel and mailed to participants. Each event produced a severity rating, description of the reason for the safety event, and a brief recommendation about how to avoid the event in the future. Subjects not owning a DVD player were provided one by the study. Compliance with review of this weekly information was assessed by a weekly telephone call or e-mail from the research assistant to determine whether the study partner and the driver had reviewed the videos and ratings, and discussed them.

2.5.6 | Post-intervention monitoring phase (months 7–12)

During this monitoring phase, all subjects continued to drive for 6 months with cameras still recording events. Participants returned for office visits at the end of year 1 for CDR restaging and MMSE. Family members completed a log of trips made/week, miles travelled/week, and any accidents during the previous year. The vehicle's odometer reading was recorded at the start and end of each study phase to estimate travel exposure.

2.6 | Analysis

We used generalized estimating equation (GEE)[32] modeling to determine the efficacy of video feedback intervention in reducing UDE frequency and severity from baseline to end of intervention. In addition, we examined whether the efficacy of the video feedback intervention was sustained at the end of a 6-month follow-up for both UDE frequency and severity. All analyses were carried out using the geepack software package in R,[33] with subject number as the cluster identifier and a working independence correlation matrix. UDE frequency was modeled via an overdispersed Poisson distribution, whereas UDE severity was analyzed as a Gaussian variable in the logarithmic scale. Exposure differences were taken into account by adjusting for miles driven via an offset variable. Degree of cognitive impairment and age were tested as moderators of the intervention in both models. An interaction test P-value $< .05$ was chosen as evidence against the null hypothesis of no moderation. Unadjusted analyses based on between-arm differences in UDE severity change scores between the baseline and intervention period are presented as well, based on a two-sample Wilcoxon test. Effect size calculations were based upon between-arm differences in log (rate ratios) across time for UDE frequency and severity per 1000 miles driven and on mean differences in change scores for total UDE severity. Effects (δ) were categorized as small (.2), moderate (.5), or large (.8) based on Cohen's nomenclature.[34]

3 | RESULTS

Table 1 describes the sample at baseline according to study arm. No significant between-arm differences emerged for any of the participant characteristics under consideration (all P's $> .29$). Both frequency and severity analyses were restricted to UDEs with severity ratings > 5. Of 11,674 events recorded during the study, 4753 were characterized

TABLE 1 Baseline characteristics of N = 51 participants randomized to either study arm

	Monitoring + feedback (n = 25) N (%) or M (SD)	Monitoring only (n = 26) N (%) or M (SD)	Statistic	*P*
Sex (%male)	18 (72.0)	14 (53.8)	$\chi^2 = 1.10$	.29
CDR (% 0.5)	18 (72.0)	16 (61.5)	$\chi^2 = 0.25$	.62
MMSE (total)	24.48 (2.89)	24.23 (3.22)	t = 0.29	.77
MCAS (total)	40.24 (6.55)	39.54 (6.90)	t = 0.37	.71
Dementia duration (months)	43.04 (28.00)	40.88 (23.91)	t = 0.30	.77
Age (years)	75.41 (7.07)	76.06 (10.02)	t = -0.27	.79
Education (years)	15.04 (2.86)	14.88 (3.75)	t = 0.17	.87
Driving experience (years)	57.56 (8.13)	57.38 (9.75)	t = 0.07	.94
Spouse as study partner	18 (72.0)	15 (57.7)	$\chi^2 = 0.60$	.44

Abbreviations: CDR, Clinical Dementia Rating; MCAS, Minnesota Cognitive Acuity Screen; MMSE, Mini-Mental State Examination.

TABLE 2 Miles driven per week during each study period

	Monitoring + Feedback M (SD)	Monitoring only M (SD)	Statistic	*P*
Baseline (1–3 months)	114 (108)	110 (126)	t = 0.10	.92
Intervention (4–6 months)	93 (101)	104 (145)	t = -0.30	.77
Follow-up (7–12 months)	70 (78)	74 (64)	t = -0.20	.84

as unsafe by the investigators. No major accidents or injuries occurred throughout the course of the study.

Table 2 describes the sample according to miles driven per week by each study arm. No significant between-arm differences were seen at any of the three study periods (baseline, intervention, and follow-up).

The total number of UDEs dropped from 778 during baseline to 723 during the intervention phase in the monitoring arm (7.1% reduction) and from 1059 to 768 in the feedback arm (27.5% reduction). Table 3 shows that UDE frequency per 1000 miles was reduced by 12% in feedback (rate ratio [RR] = 0.88, 95% confidence interval [CI] = .58–1.34), while remaining approximately constant with monitoring alone (RR = 1.01, 95% CI = .68–1.51). The ratio of these two rate ratios (RRR = .87, 95% CI = .49–1.55) captures differences in the effect of feedback over monitoring across study phases and corresponds to a small effect size ($\delta = .13$, $P = .63$). Baseline age and cognitive impairment were tested jointly as moderators of intervention effects on UDE frequency, correcting for miles driven. Although age ($P = .15$) was not a statistically significant moderator, MCAS total score was ($P = .03$) and both its main effect and interaction with feedback were entered as predictors in the Poisson regression model. Higher baseline cognitive function, as captured by higher MCAS scores, was protective in feedback ($P = .006$), with a one-quartile increase in MCAS score away from the median (i.e., from 40 to 43 points) leading to a 14% reduction in UDE rates (RR = .86, 95% CI = .78–.96), but had no effect in monitoring ($P = .49$), while the same increase in MCAS score resulted in just a 2% reduction in UDE rates (RR = .98, 95% CI = .93–1.03). Essentially, feedback benefited most those best able to take advantage of it, (i.e., less cognitively impaired participants).

The total severity points for UDEs dropped from 7690 to 7066 (8.1% reduction) in the monitoring arm and dropped from 9866 to 7253 (26.5% decline) in the feedback arm, for a total relative reduction for feedback over monitoring of 18.4%. Table 4 shows that UDE severity score per 1000 miles was reduced by 37% from baseline in feedback (RR = 0.63, 95% CI = .31–1.27), but increased by 40% in monitoring (RR = 1.40, 95% CI = .68–2.90). As above, the ratio of these rate ratios (RRR = .45, 95% CI = .16–1.23) captures differences in the effect of feedback over monitoring across study phases and corresponds to a moderate effect size ($\delta = .46$, $P = .12$). After correcting for miles driven, baseline age and cognitive impairment were again tested as moderators of intervention effects on UDE severity. Neither age nor MCAS total score met moderation criteria. However, age was borderline significant in the monitoring arm ($P = .07$), but not significant in the feedback arm ($P = .47$). Hence, we decided to estimate its arm-specific effects in an exploratory fashion. Both its main effect and interaction with feedback were entered as predictors in the Gaussian regression model. Findings suggested that older age was a strong risk factor in the monitoring arm, with a one-quartile increase away from the median (i.e., from 76 to 82 years) leading to an 85% increase in UDE severity (RR = 1.85, 95% CI = .95–3.60), compared to a smaller 28% increase in UDE severity (RR = 1.28, 95% CI = .65–2.50) seen in the feedback arm. In that sense, feedback mitigated the adverse effect of age on UDE severity.

TABLE 3 Unsafe driving event (UDE) rate per 1000 miles driven by study period

	Baseline (1–3 months)		Intervention (4–6 months)		Follow-up (7–12 months)	
Study arm	Rate	95% CI	Rate	95% CI	Rate	95% CI
Monitoring + Feedback	28.67	(14.93, 55.05)	25.29	(11.80, 54.20)	23.71	(9.93, 56.63)
Monitoring only	21.13	(12.92, 34.57)	21.44	(12.39, 37.08)	12.24	(5.01, 29.88)
Ratio	1.36	(.60, 3.07)	1.18	(.46, 3.02)	1.94	(.56, 6.74)

TABLE 4 Unsafe driving event (UDE) severity score per 1000 miles driven by study period

	Baseline (1–3 months)		Intervention (4–6 months)		Follow-up (7–12 months)	
Study arm	Severity	95% CI	Severity	95% CI	Severity	95% CI
Monitoring + feedback	128	(66, 247)	81	(30, 219)	143	(56, 363)
Monitoring only	114	(48, 271)	160	(63, 405)	38	(12, 123)
Ratio	1.12	(.38, 3.31)	.51	(.13, 1.97)	3.72	(.84, 16.55)

Figure 2 depicts the totals for UDE severity according to individual error categories. Comparing changes in monitoring versus feedback, reductions between the baseline and intervention phases were greater for feedback for all categories of driving errors except distracted driving. Total UDE severity points across all error categories declined on a per driver basis from 395 points to 290 points in the feedback arm and from 308 points to 283 points in the monitoring arm. The resulting 80-point difference between the decline in the feedback (mean = 105, standard deviation [SD] = 186) and monitoring (mean = 25, SD = 201) arms corresponds to a moderate intervention effect ($\delta = .41$, $P = .06$) when expressed in terms of the pooled standard deviation of the change scores (SD = 196).

During the follow-up period, the feedback group continued to demonstrate reductions in UDE frequency from baseline (RR = 0.83, 95% CI = .36–1.87), partially countered by small increases in UDE severity (RR = 1.11, 95% CI = .49–2.52). In contrast, monitoring showed large drops in both UDE frequency (RR = 0.58, 95% CI = .25–1.32) and UDE severity (RR = .33, 95% CI = .10–1.08) from baseline. However, as indicated by Figure 1, non-differential attrition rates of more than 50% of the randomized sample during follow-up point to the possibility of selection bias in these findings, which should be interpreted with caution.

No differences emerged in 12-month driving-cessation rates (feedback = 28.0% vs. monitoring = 38.5%; $\chi^2[1] = .25$, $P = .62$). Figure 3 shows Kaplan–Meier survival curves for each study arm. A log-rank

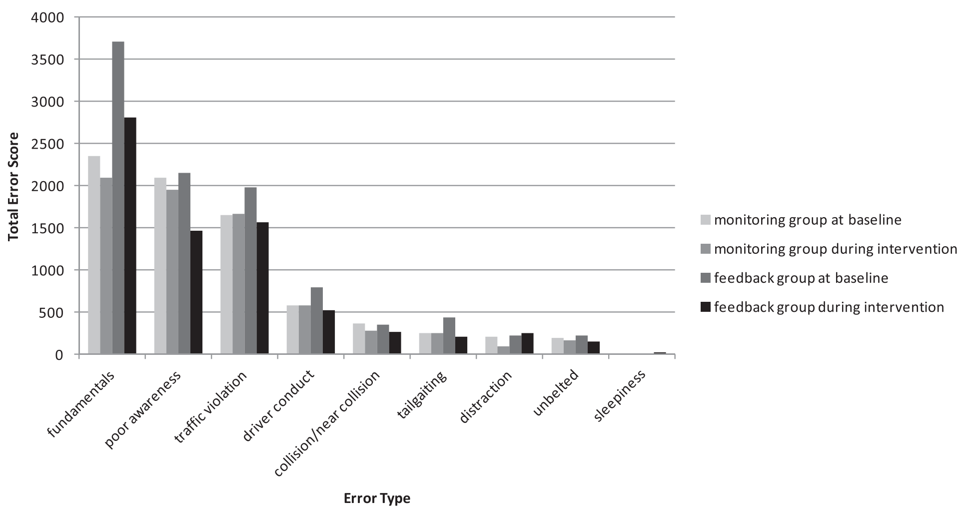

FIGURE 2 Total unsafe driving event severity according to driving error categories. Error types: fundamentals (fail to keep an eye out, too fast for conditions, unsafe lane change); poor awareness (not looking far ahead, blank stare, not scanning roadway, not scanning intersection, mirrors not checked); traffic violations (rolling stop, stop sign, red light, not on designated highway, speeding, other); driver conduct (judgment error, aggressive, reckless); collisions (or near collisions); following too close/tailgating; distractions (cell phone, other communication devices, food or drink, electronic devices passenger); unbelted; and sleepiness while driving

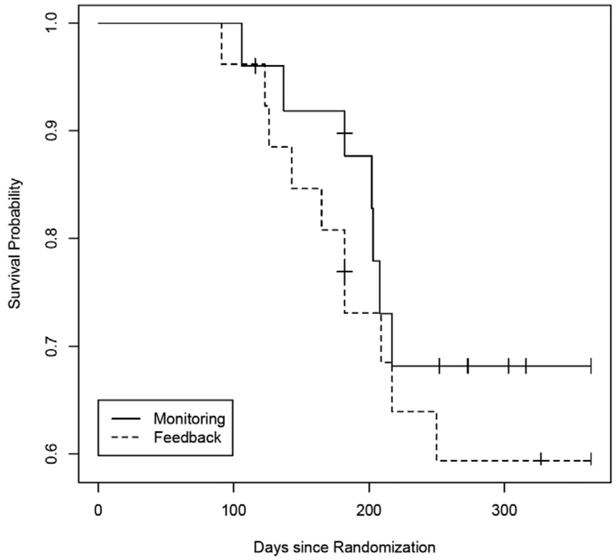

FIGURE 3 Kaplan–Meier survival curves showing time to driving cessation by study arm

test comparing time to driving cessation across the two study arms was not significant ($\chi^2[1] = .54$, $P = .46$).

Weekly compliance with reviewing weekly driving reports was reported to be consistent throughout the intervention period by all participants, while compliance with reviewing the videos was variable in five participants. Compliance was not significantly related to sex, age, education, AD diagnosis, global CDR, MCAS total score, or MMSE score, nor was it significantly related to study partner sex, relationship, or hours spent per week with the participant.

4 | DISCUSSION

In this controlled clinical trial, feedback about driving errors through videos and written recommendations was associated with improvement in driving skills as measured by both a reduction in frequency and severity of safety errors during the intervention phase. In contrast, drivers who were monitored with no feedback showed no change in number of driving errors and an increase in overall driving error severity when adjusted for miles driven. To our knowledge, this is the first study to attempt to improve the driving practices of cognitively impaired elders using video feedback technology.[1]

We were also able to document unsafe driving behaviors in a naturalistic setting that might not have been observed in the typical 1-hour standardized road test. In-car safety technology is expanding and could further enhance safety. This study offers one such approach to maintaining one of the most complex and important activities of daily living for this group of elders.

Results are in line with data from two longitudinal monitoring studies showing that the majority of drivers with MCI or mild AD continue to drive and can pass a standardized road test, despite their increased risk for motor vehicle crash.[35,36] The majority (67%) of our participants continued to drive over the 1-year study period. Studies on behavioral interventions designed to improve or maintain driving, however, are limited. An evidence-based review of interventions for medically at-risk older drivers in 2014[1] found no reports of clinical trial interventions to improve the driving abilities of cognitively impaired elders. For people with dementia, authors recommended driving restriction interventions and made no recommendation for or against the use of compensatory driving strategies. In 2019, a randomized controlled trial was reported by Shimada et al. [37] that examined a safe driving skill program consisting of classroom and on-road training. One hundred and sixty community-living older drivers with MCI participated. Group by time interactions indicated benefits of the intervention over time. Our results also suggest a behavioral modification program targeted at drivers' own errors may extend cognitively impaired drivers' ability to drive independently.

In addition to behavioral modification, cholinesterase inhibitors (ChEI) may improve driving performance. We conducted a combined observational cohort and case-control study in patients with AD and found that ChEI treatment enhanced simulated driving accuracy and visual search target detection accuracy and response time in both pre-ChEI–post-ChEI and users–nonusers treatment comparisons.[38] No studies to our knowledge have evaluated combined medication and behavioral interventions on driving.

4.1 | Limitations

One of the limitations of our study design was the absence of coaching and verbal feedback between the research staff and the driver/family member to reinforce understanding and significance of the observed unsafe driving events. This may have contributed to the lack of a sustained treatment effect in follow-up that we were previously able to demonstrate in our pilot study with an enhanced intervention combining active coaching with written materials.[24] Future intervention designs should consider incorporating caregiver training and/or providing ongoing feedback rather than just 3 months of feedback.

Additionally, with N = 25/subjects per group, the study was designed to detect large intervention effects ($\delta = .80$), whereas the observed effect sizes were in the small-to-moderate range ($\delta = .13$–$.46$). Further, to take into account driving exposure differences between subjects, we adjusted for miles driven according to their odometer readings and estimated time driving from the study partners when vehicles were driven by more than one. Such estimates may have reduced the accuracy of our behavioral assessments, and examination of the total safety demerit scores by treatment group in Figure 2 may actually provide a more accurate view of the feedback intervention effect. Finally, drivers were variably adherent to viewing videos, and this factor may have attenuated the feedback effectiveness.

5 | CONCLUSIONS

The results of this clinical trial show the potential to improve driving safety among older drivers with cognitive impairment using a behavior modification approach aimed directly at the problem behaviors observed in their natural driving environment. It is impractical and cost prohibitive to propose implementing a sustained individual feedback program on a large scale. In this regard, our study provides an impetus for the auto industry to develop similar in-car continuous video and voice warning feedback systems to promote the safety of older drivers. Other feedback and safety monitoring systems are under development for government and commercial driving fleets,[39–41] which may have future applicability to older drivers.

Knowledge gained from this project about the magnitude and duration of the treatment effect will hopefully provide the impetus to optimize and implement this type of technology to improve the safety of older drivers with MCI and early AD who may need continuous feedback on their driving to produce behavior change. Successful implementation of video feedback technology into the current design of vehicles driven by cognitively impaired older drivers would enhance public safety on our roads and maximize the time for independent driving, improving the overall quality of life of these individuals.

ACKNOWLEDGMENT

The results of this study were presented at the Alzheimer's Association International Conference on July 29, 2020.

CONFLICTS OF INTEREST

None of the authors have any conflicts of interest to disclose related to this research or the manuscript.

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How to cite this article: Ott BR, Papandonatos GD, Burke EM, Erdman D, Carr DB, Davis JD. Video feedback intervention for cognitively impaired older drivers: A randomized clinical trial. *Alzheimer's Dement*. 2021;7:e12140.
https://doi.org/10.1002/trc2.12140