

Table of Contents

Supporting Statement

Justification

- B.1 Describe the potential respondent universe and any sampling or other respondent selection to be used.
- B.2 Describe the procedures for the collection of information.
- B.3 Describe methods to maximize response rates.
- B.4 Describe any tests of procedures or methods to be undertaken.
- B.5 Provide the name and telephone number of individuals consulted on statistical aspects of the design.

Supporting Statement

B. Collections of Information Employing Statistical Methods

NHTSA is seeking approval to conduct a quasi-experimental study to gather objective data regarding the effects of physical activity on driving performance and exposure.

For Phase I of this study, 60 participants age 70 and older who have been actively engaged in physical fitness activities for at least six months and 30 sedentary “controls” also age 70 and older who have not been actively engaged in physical fitness activities for at least six months will be recruited to participate in this study and complete a clinical functional evaluation, a driving evaluation, wear a pedometer, and allow data collection devices to be installed in their personal vehicles to collect driving exposure data for one month. For Phase II of this study 180 sedentary participants age 70 and older will be recruited and complete the same activities as described above; however 30 will serve as controls and 60 will engage in one of two physical fitness programs for a 6-month period. All 180 participants in Phase II will repeat the driving evaluations after 6-months and have their driving exposure monitored for one month, and wear the pedometers to record their physical activity.

All participants will be recruited through public solicitations to residents of one or more planned communities in the vicinity of Chapel Hill, North Carolina. Solicitations will be in the form of flyers posted at a community center, and/or announcements in newsletters and on community listservs, and/or sign-ups at a weekly farmer’s market and other local events. Interested residents will contact a designated NHTSA research team member through a toll-free telephone number to enroll. During a brief telephone pre-screening, a project assistant will explain inclusion and exclusion criteria for study participation. Candidate participants who meet these criteria may be enrolled in the study.

To ensure prospective participants meet inclusion criteria, the researchers will ask the following questions of each respondent to the solicitation:

1. Do you own or have possession and use of a car?
2. Do you have a valid driver’s license, and if so, when does it expire?
3. What is your date of Birth?
4. About how many times per typical week do you drive your car?
5. Have you been diagnosed with any medical condition for which your doctor has advised you to limit or adjust your driving habits?
6. Do you use adaptive controls in your car?
7. Will you be spending the next two or three months in the area?

A research team member will call back qualified participants and ask them to:

- 1) Travel to the DRS’s office to complete functional testing and a driving evaluation, and to have a data acquisition system (DAS) installed in their vehicle;
- 2) Drive their vehicle as customary for a period of one month; and

3) Return to the DRS's office so that the research team can remove the DAS.

Data Analysis Plan

Questionnaire responses will only be used to establish participants' eligibility; they will not be analyzed. The focus of this study will be to compare driving performance (as measured by a driving rehabilitation specialist (DRS) and exposure (as measured using a DAS installed in participants' own vehicles) of older drivers who are sedentary to that of participants of similar age who are physically fit.

Driving behaviors observed/scored during the CDRS evaluation will include (but not be limited to):

- Speed compared to that of surrounding traffic;
- Stopping at inappropriate times or locations;
- Intersection navigation performance;
- Managing lane changes;
- Maintaining appropriate speed;
- Accelerating and braking smoothly;
- Blind spot checks when merging, changing lanes, and backing out of parking spaces;
- Vehicle control when backing.

Driving exposure measures will include number and duration of trips during a one-month period, including average and maximum trip length, categorizing trips according to road type (residential, arterial, freeway, and/or by posted speed limit), and weather/visibility conditions (wet/dry, day/dusk/night). In addition, driver behaviors associated with safe performance that logically should be affected by fitness level will be recorded by the planned in-car instrumentation, for example, mirror checks and shoulder checks.

A data analysis plan outlining the performance measures that will be compiled and the proposed statistical methods will be developed and submitted to NHTSA. The proposed statistical methods will depend on the specific performance measure and whether it is continuous data, count data, ordinal data, etc. Methods such as t-tests, ANOVA, and linear regression will be appropriate for continuous data. On the other hand, count and ordinal data will be analyzed using chi-square tests and logistic/Poisson/negative binomial regression methods.

B.1. Describe the potential respondent universe and any sampling or other respondent selection to be used.

The potential respondent universe is comprised of all drivers age 70 and older who reside in or near Chapel Hill, NC, have access to a motor vehicle and hold a valid driver's license, and who do *not* (1) have any (self-reported) medical condition (e.g., sleep apnea) that could potentially interfere with driving performance or exposure, or (2) use any adaptive vehicle controls. From this universe, the new data collection (telephone

interview) will qualify 60 drivers who have been active in fitness activities for at least six months when they join the study; and 120 ‘sedentary’ drivers who have *not* been active in any regular fitness activities for the past 6 months, half (60) of whom will participate in a fitness training class as part of the study.

Potential Respondent Universe

Group, Licensed Drivers 60+	Universe	N Contacted	Expected Response Rate	Sample
Physically active	265,000	90	67%	60
Not physically active	265,000	180	67%	120

B.2. Describe the procedures for the collection of information.

NHTSA’s research team will coordinate with social, recreational, and wellness directors at planned communities in the Chapel Hill, NC, vicinity, to utilize community newsletters and other community media to advertise the opportunity to participate in this research project. These media will invite interested residents to contact a designated research team member for more information, using a toll-free number. When such individuals call to learn more about the study, we will conduct the planned telephone interview to determine whether they qualify for study participation, based on their current driving habits, and self-reported medical/physical condition and level of physical activity they engage in on a regular basis.

B.3. Describe methods to maximize response rates.

Participation in this study is voluntary. To maximize response rates we will rely on the active support of cooperating individuals in planned communities who direct social, recreational, and wellness programs who will promote study participation. These individuals will understand that this research will support their mission to help the residents of their communities remain safely mobile, which is vital to healthy aging. At the same time, their existing relationships with their residents, in familiar and trusted roles, should help maximize response rates.

We also will attempt to maximize response rates by offering financial incentives to respondents if they qualify for study participation. We will pay \$100 to all study participants, for allowing instruments to be placed in their own cars for a month to monitor their driving habits and travel patterns. Experience has shown that this level of incentive is necessary to successfully recruit participants in a study such as this one. For a subset of ‘sedentary’ study participants, we will offer free enrollment in a fitness training program with a value of \$300-\$400.

Additionally, we will provide written assurances of confidentiality, such that no individual will be identified in reports of the study's findings, nor will any driver's data be shared with any licensing regulatory authority.

B.4. Describe any tests of procedures or methods to be undertaken.

We do not anticipate substantive changes to the planned telephone interview method that we expect to average 15 minutes in length across respondents. However, we intend to remain sensitive to the nature of responses we receive and will respond with modest changes as needed to meet our participant counts.

B.5. Provide the name and telephone number of individuals consulted on statistical aspects of the design

The following individuals have reviewed technical aspects of this research plan:

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