4.0 Subjects

4.1 Informed consent

The subjects solicited for the study were experienced, licensed truck drivers working for either of two shipping companies (one in Canada and one in the U.S.), operating revenue delivery runs. For the dual purposes of compliance to protocol and risk mitigation, as well as the requirement that trucks be extensively instrumented for the study, drivers were solicited from only these two companies, both of which had excellent safety records. Driver solicitation was carried out only after the management of the companies gave permission for the study to be conducted on their drivers and trucks. However, it is important to note that while company management assisted in identifying potential volunteer drivers, they had no requirement for any driver to volunteer or participate in the project. Drivers' participation in the project was strictly voluntary and had no bearing on the nature of their work, their pay or their relationship with management. Drivers were not compensated beyond their normal wages for participation in the study. They were each given a baseball hat, tee shirt, and tire gauge, as token gifts for participating in the study. All data acquired were kept in strictest confidentiality, and were not available to the companies. Fully informed consent was obtained from all volunteer drivers, and drivers were aware they could withdraw from the protocol at any time without jeopardy of job, pay or any other factor. Canadian drivers' voluntary participation in the study met all requirements of the Canadian Research Ethics Board, while U.S. drivers' voluntary participation in the study met all requirements of the Institutional Review Board of Walter Reed Army Research Institute. The protocol and informed consent forms was fully reviewed and approved separately by each of these Human Research Ethics Boards. No adverse events occurred during data acquisition in either Canada (Study Phase 1) or in the U.S. (Study Phase 2).

It is important to note that there is a vast array of practices in the amalgam referred to as "the trucking industry." This pilot study did not seek to investigate every type of trucking operation or practice, nor did we intend the results to generalize to all aspects of the trucking industry in either Canada or the United States. Rather, the focus was specifically on determining whether FMT FEEDBACK affected truck drivers' behaviors, and how they perceived the fatigue management technologies in the study.

4.2 Sample size relative to study design

The original project plan was to investigate the effects of FMT FEEDBACK in a total of n = 48 driver volunteers studied for a 2-week period (1 week in the NO FEEDBACK condition and 1 week in the FEEDBACK condition). Early on, however, concerns about volunteer rates, subject attrition, study equipment failures, and other factors associated with loss of data, as well as the limited resources and fixed timeline for the study, resulted in a design modification. The needed sample size was reduced to n = 24, but the periods for NO FEEDBACK and FEEDBACK were doubled to 2 weeks each. This resulted in no change in the total number of subject days FMT monitoring would occur in the study (i.e., n = 48 drivers x 14 days of monitoring for each = 672 subject days; versus n = 24 drivers x 28 days of monitoring each = 672 subject days). In addition, we markedly increased the resolution of the monitoring of driver and truck variables by using a black box recorder (AP+ see section 5.2.1) that recorded every variable every second a driver was driving (the original plan was to use 1 minute as the smallest temporal unit).

Thus, by using n = 24 subjects as their own controls, and ensuring a 60-fold increase in temporal resolution for driver and truck monitoring, over double (28 days) the number of days originally planned (14 days), we optimized the feasibility of the study relative to available resources and time, and minimized the risks posed to hypothesis testing by loss of data due to inadequate volunteering and equipment failure. This approach however, resulted in 60 times the volume of data than originally planned. That is, it yielded many millions of data values (on driver and truck performance variables), which we believe is the largest database ever to be objectively recorded for working truck drivers. Such a massive dataset required extensive data quality control procedures, which were implemented and followed throughout the study. As a result, a great deal of the reduced data results is contained in the more than 150 tables in Appendices C-F.

4.3 Number of drivers volunteering in each study phase

A grand total of n = 39 drivers volunteered for the study (n = 27 from Challenger Motor Freight, Ontario, Canada; and n = 12 from Con-Way Central Express, Ann Arbor, Michigan, U.S.). One driver dropped out after being empanelled, which reduced the Canadian sample to n = 26 (20 males, 6 females), and the total sample to n = 38. Demographics characteristics of the volunteers as they pertain to truck driving experience are shown in Table 1. More drivers were empanelled than the target sample size of n = 24

Table 1: Characteristics of the Canadian and U.S. Truck Drivers Participating in Study

Country	n =	Sex	Age mean (yr)	Age range (yr)	Years at company (mean)	Years at company (range)	Years driving large trucks (mean)	Years driving long haul (mean)	Miles driven last year (mean)
Canada	20	M	45.4	22-58	4.6	< 0.5 – 17	16.6	11.3	> 109K*
Canada	6	F	35.3	22-50	4.0	< 0.5 – 15	2.1	1.6	> 76K

U.S.	12	M	46.9	32-57	11.5	6.5 – 18	23.7	18.0	> 99K
TOTAL	38	84% male	44.2	22-58	6.7	< 0.5 – 18	16.6	11.9	> 100K

*based on n = 18 (data missing from 2 male drivers)

due to the need to compensate for the loss of data due to equipment failure. Equipment failure (see report Section 5.3) during the 4-week data acquisition study reduced specific comparisons between FEEDBACK and NO FEEDBACK conditions on some variables to sample sizes ranging between n = 15 and n = 25 drivers in the Canadian study phase, and between n = 7 and n = 12 drivers in the U.S. study phase. Therefore, when combining study phases, the hypothesis-testing sample size ranged between n = 22 and n = 38, depending on the variable being analyzed. As shown in Table 1, the majority of participating drivers were middle-aged males with many years experience driving long-haul.