3.0 Study Design

The primary goal of the study was to determine whether information feedback from a combination of the more promising fatigue management technologies would (1) enhance truck driver alertness, especially during night driving, and (2) increase sleep time, while driving under current hours-of-service in the United States and Canada. As noted above, since it was neither cost-effective nor practical to conduct a separate study of each individual technology, the selected representative four FMT technologies were combined and tested as a set within in a single field trial that had two phases. Study Phase 1 (data collection in 2002) took place under Canadian hours-of-service, and involved a Canadian trucking company (Challenger Motor Freight, Ontario, Canada) in which volunteer drivers operated single tractor-trailer units with sleeper berths, and approximately 74% of their driving was conducted during daylight hours. Study Phase 2 (data collection in 2003) took place under U.S. hours-of-service, and involved a U.S. trucking company (Con-Way Central Express, Ann Arbor, Michigan) in which volunteer drivers operated tandem tractor-trailer units without sleeper berths, and approximately 93% of their driving was conducted during nighttime hours. The difference between Canadian and U.S. trucking companies were in part a function of which companies agreed to be part of the study, as well as our goal to expressly study companies in which night driving was both a minority (Study Phase 1) and a majority (Study Phase 2) of trucking operations.

To compare the effects of feedback from combined fatigue management technologies with no feedback from FMT technologies, a within-subjects cross-over design was used in both phases (countries) of the study. The design did not require manipulating or controlling what the participating companies and drivers did, what schedules the drivers adhered to, or what operating practices they actually followed. Rather, the FMT intervention and data collection were applied to existing routine trucking operations. Thus, for the comparisons of the effects of FMT FEEDBACK vs. NO FEEDBACK, volunteer drivers served as their own controls—undergoing both conditions under nearly identical circumstances.

Each driver underwent the two conditions in the same order: 2-weeks of the NO FEEDBACK (baseline control condition) occurred first, followed by 2-weeks of the FMT FEEDBACK (intervention condition). Condition order was not counterbalanced because providing the NO FEEDBACK condition after the FEEDBACK condition would have involved a change in driver behavior carried over from the FEEDBACK condition (i.e., drivers might have opted to turn on the feedback information from devices while in the NO FEEDBACK condition). In contrast, by providing the NO FEEDBACK condition first, drivers engaged in their normal driving practices for 2 weeks, although their driving performance, drowsiness and sleep need were still recorded by the relevant FMT technologies (i.e., FMT devices were recording but not providing feedback). The NO FEEDBACK condition therefore served as a baseline against which the FMT FEEDBACK intervention was compared. Again, each driver participant was scheduled to undergo each condition (NO FEEDBACK and FEEDBACK) for a period of 14 days per condition (i.e., approximately 28 days total for study participation).

There were a number of considerations that went into selecting a design to address the specific aim and hypothesis. A cross-over (or treatment-by-treatment) design uses subjects as their own controls. It is efficient, and it has a number of advantages over an independent-groups design. It ensures roughly the same inter-subject variability across both conditions (by and large the results of the study confirm this was the case). It provides an opportunity for subjects to explicitly compare and contrast conditions. It requires fewer subjects than an independent-groups design, which makes it more feasible from both cost and timeline perspectives. On the downside, a cross-over design necessarily burdens a smaller group of subjects with more recording time than would be the case in an independent-groups design. If too burdensome, subjects may fail to complete all conditions. This occurred to some extent in both phases of the present study, but was not a major problem.

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