1. Title: Evaluation of Fatigue in Short-Haul Operations Across Multiple Airlines

2. Organizations and Study Location(s): The research described will be performed by investigators at NASA Ames Research Center (ARC) in collaboration with researchers at the Civil Aerospace Medical Institute (CAMI), Washington State University (WSU), and Brigham and Women's Hospital (BWH). Due to the nature of the project, field data will be collected throughout the United States (US).

3. Investigator:

Erin E. Flynn-Evans, PhD MPH
NASA Ames Research Center
Human Systems Integration Division
Mail Stop 262-4, Code TH
Moffett Field, CA 94035
Phone: (650) 279-3459
Fax: (650) 604-3729
Email: erin.e.flynn-evans@nasa.gov

Co-Investigators:

Cassie J. Hilditch, PhD
San José State University
NASA Ames Research Center
Human Systems Integration Division
Mail Stop 262-4, Code TH
Moffett Field, CA 94035
Email: cassie.j.hilditch@nasa.gov

Nicholas G. Bathurst, MA
NASA Ames Research Center
Human Systems Integration Division
Mail Stop 262-4, Code TH
Moffett Field, CA 94035
Email: nicholas.g.bathurst@nasa.gov

Collaborators:

Thomas Nesthus, PhD
FAA Aviation Safety
Civil Aerospace Medical Institute (CAMI)
Oklahoma City, OK 73169
Email: tom.nesthus@faa.gov

Hannah Baumgartner, PhD
FAA Aviation Safety
Civil Aerospace Medical Institute (CAMI)
Oklahoma City, OK 73169
Email: hannah.m.baumgartner@faa.gov

Amanda Lamp, MS, PhD
Washington State University (WSU)

Occupational Sleep Medicine Group
Email: alamp@wsu.edu

Laura Barger, PhD
Brigham & Women's Hospital
Harvard Medical School
Division of Sleep Medicine
Boston, MA 02115
Email: laura_barger@hms.harvard.edu

Heather Provost
Senior Manager, Fatigue Risk Management
American Airlines
Fort Worth, TX 76155
Email: heather.provost@aa.com

Fatigue Countermeasures Laboratory Study Staff:
Lucia Arsintescu (SJSU Research Foundation)
Kevin Gregory (NASA)
Nathan Feick (SJSU Research Foundation)
Crystal Kirkley (NASA)
Gregory Costedoat (SJSU Research Foundation)
Zachary Glaros (NASA)
Sean Pradhan (Menlo College)
Rachel Jansen (SJSU Research Foundation)
David Rockman (SJSU Research Foundation)
Michelle Tripp (SJSU Research Foundation)

WSU Research Team:
Kylee Dawn Amos
Michael Rempe
Ian Rasmussen

AA Research Team:
Lucas Johnson

4. Purpose

This research is being conducted as a component of a Reimbursable Interagency Agreement between NASA and CAMI (IAA No. SAA2-403611). The purpose of the present study is to collect objective and subjective measures of sleep, sleepiness, performance, and workload that can be used to assess fatigue levels of short-haul pilots during normal operations.

5. Background

Aviation regulation and safety oversight is in an era of performance-based risk management. Research is ongoing to understand the role fatigue plays in degraded human performance during various types of operations within the aviation system. As part of this process, the Federal Aviation Administration (FAA) proposed duty limits and rest requirements which went into effect in 2014 (Code of Federal Regulations [14 CFR] Part 117, 2012). A study of fatigue in short-haul operations under these regulations is yet to be conducted. Recently, the FAA proposed the need for research to evaluate fatigue within these regulations in short-haul operations.

Determinants of Alertness and Performance in Short-Haul Aviation Operations

There has been a great deal of research to understand the influence of factors such as circadian misalignment induced by jet lag during long-haul flights on pilot fatigue and performance, but comparatively fewer studies have been conducted to evaluate fatigue and performance among pilots during short-haul operations. There are several factors that have the potential to reduce alertness and performance among airline pilots during short-haul operations, including time of day, time awake, workload, and consecutive work shifts. Each of these factors can influence a pilot's fatigue and performance, and in combination, these factors have the potential to cause severe performance impairment.

Time of Day. The circadian rhythm promotes waking during the biological day and sleep at night. When individuals who are normally awake during the day and sleep at night have to engage in night work, the sleep drive is strongest and performance is worst during the hours of 0200 to 0559, a time that has been dubbed the Window of Circadian Low (WOCL; Scientific Principles for Fatigue Management, 2015). Prior studies confirm that micro-sleeps and fatigue ratings are highest during night flights (Samel et al., 1997), whereas performance is relatively stable during short-haul flights that occur during the day when the circadian rhythm is strongly promoting wakefulness (Flynn-Evans et al., 2018).

Start Time of Duty and Time Awake. The start time and time awake prior to a flight can also influence an individual's ability to obtain adequate sleep and maintain subsequent performance. Consecutive early work start times can lead to WOCL encroachments and lower quality sleep (Roach et al., 2012; Flynn-Evans et al., 2018), while later report times could mean pilots may wake several hours prior to their actual duty, increasing time awake before performing critical tasks (Rosekind et al., 1994; Samel et al., 1997; Gander et al., 1998; Caldwell et al., 2006; Vejvoda et al., 2014). Indeed, short-haul pilots who start work in the morning after 0900 have been shown to achieve more sleep (Roach et al., 2012; Flynn-Evans et al., 2018).

Flight Segments. Workload can also influence a pilot's fatigue level. Several studies have demonstrated that flying three or more flight segments in a single duty day is associated with increased subjective ratings of fatigue and poorer performance (Bourgeois-Bougrine et al., 2003; Powell et al., 2007; Honn et al., 2016).

Consecutive Operations. Several studies have demonstrated that working consecutive days is associated with poorer performance. For example, Flynn-Evans et al. (2018) found that pilots performed worse with each consecutive day of flying when scheduled for early starts, long midday flights, and late finishing daytime flights.

Preliminary Data: Focus Group Study

In order to identify fatigue factors of greatest importance to study, we conducted a series of focus groups across four major commercial passenger airlines in the United States. This study revealed several operations that pilots identified as fatiguing (Table 1). We combined these themes into six over-arching categories including: circadian disruption, high workload, rest opportunity, schedule changes, regulations, and long sits. While categories provide a useful summarization of the overall content, the value of the qualitative approach is the resolution of data at theme and code level. Therefore, core *themes* and CODES contributing to these categories are described below.

Table 1. Themes ranked by frequency of codes within each theme.

Theme	**N**	**%**
Circadian switches	171	10.5
Rest duration (layover)	153	9.4
High workload / Hassle factors	151	9.3
Number of flights	121	7.4
FAR 117 issues	93	5.7
Long sits	85	5.2
Redeyes	83	5.1
Unpredictability	79	4.9
Aircraft & crew swaps	73	4.5
Rest timing	73	4.5
Out-of-hours work	68	4.2
Early duties	64	3.9
Short turn time	53	3.3
Length of duty	46	2.8
Rest quality	45	2.8
Schedule design	38	2.3
Trip length	37	2.3
Late duties	25	1.5
Fatigue calls	24	1.5
Length of flights	20	1.2
Rest - Circadian disruption	20	1.2
Deadhead	14	0.9
Total	1625*	

Note: * = total includes codes that did not fit a defined theme. Percentage column reflects the proportion of all codes counted within each theme.

Circadian disruption. This category includes all themes related to inconsistent schedules (*Circadian switches*), duties outside of daytime hours (*Redeyes, Early duties, Late duties, Out-of-hours work*), rest opportunities during the day (*Rest timing*), and rest breaks that involve a circadian switch between duties (*Rest – circadian disruption*).

The most common theme identified overall, *Circadian switches*, refers to changes in duty start times within a trip, for example switching from an early start time to a late start time. This theme was made up of codes including: CIRCADIAN SWAPS (34% of codes in this theme), INCONSISTENT DUTY TIMES

(25%), and SWITCHING TIME ZONES (18%). SWITCHING TIME ZONES refers to the sentiment that while a schedule may look consistent based on local departure times, similar local start times in different time zones could lead to circadian shifts of up to three hours. For example, a west coast-based pilot may start day 1 of a trip at 0600h on Pacific Time (PT) and then have a 0600h report time on day 2 on Eastern Time (ET), which is effectively 0300h PT.

High workload. This category includes all themes related to increased workload such as *High workload & hassle factors, Number of flights, Aircraft & crew swaps, Short turn times*, and *Length of flights*. The third most common theme identified overall was *High workload & hassle factors*, which refers to a collection of operational challenges contributing to fatigue. Often these factors add to overall workload through increased mental effort or creating time pressure and not allowing for mental recovery during or between flights. Some factors also extend duty times, leading to extended time awake and reduced rest opportunity. This theme was made up of codes including: WEATHER (30%), MAINTENANCE (19%), GROUND OPS (18%), and BUSY AIRPORTS/REGIONS (14%).

This category also includes the fourth most common theme, *Number of flights*. This theme refers to the number of flights within a duty period. While long-haul operations typically only involve one flight within a duty period, short-haul operations typically include two or more flights within a duty period. Most responses within this theme (41%) indicated that duty periods with more than four flights were considered fatiguing. However, approximately one-third (36%) of the codes in this theme indicated a preference for duty periods with two or fewer flights in order to avoid fatigue, with a quarter (23%) suggesting that any duty with more than one flight is automatically fatiguing due to the nature of the operations.

Rest opportunity. This category includes themes related to rest opportunities independent from the timing of those opportunities (see **Circadian disruption** for *Rest timing*) including *Rest Duration (Layover)* and *Rest quality*. *Rest quality* covered codes related to hotel sleep environment (e.g., noise, temperature). *Rest duration (layover)* was the second most common theme and refers to insufficient rest opportunity between duties. This theme was made up of codes including: SHORT REST (42%), and PERSONAL TIME (30%). SHORT REST referred to comments indicating that the FAR 117 minimum rest requirement of 10 hours is too short for sufficient sleep opportunity. PERSONAL TIME includes comments regarding the need for time to eat, exercise, wind down, and prepare for the next duty within the allocated rest period. In a short rest period, often there is not enough time for all these factors, leading to skipping important daily needs and/or reducing the amount of time available for sleep.

Schedule changes. This category emerged from the theme, *Unpredictability*, which covered codes such as SCHEDULE CHANGES (43%), PLANNED VS OPS (29%, planned schedules being different to operational reality), and EXTENSIONS and DIVERSIONS (28%). Schedule changes affected fatigue by extending flight or duty time, adding workload, and/or changing the timing of duty and rest opportunities.

Regulations. This category includes the fifth most common theme, *FAR 117 issues*, as well as *Fatigue Calls*. *FAR 117 issues* refers to comments from participants regarding the regulations (FAR 117) dictating the current flight, duty, and rest time requirements and how they are implemented. Thirty-seven percent of the codes in this theme related to the use of FAR regulations by airlines as goals or targets, rather than limits. A further 24% recommended revisions to the regulations in order to effectively manage fatigue. Some participants felt that the scheduling software used to create pairings lacked human insight into obviously fatiguing duties and trips. With regard to *Fatigue Calls*, participants commented on barriers to submitting fatigue calls (BARRIERS, 42%) such as lack of pay protection and the drive to “get the job done”. A third of codes in this theme (RESPONSIBILITY, 33%) reflected the pilots’ disagreement with the fatigue call system putting the responsibility on the pilot to call out fatigued, and felt that more responsibility should lie with the airline to provide less fatiguing schedules.

Long sits. This category emerged from the theme, *Long Sits*, which in turn was derived from the code LONG SITS. Sit time refers to the time between flights within a duty during which the pilot has to wait in the airport until the next flight. The general consensus among participants was that a long sit would be defined as a sit time greater than 2 hours. The concept of long sits was so prevalent in the transcripts, that despite not being merged with any other codes, it was the sixth most common theme. The concept was also unrelated to the other themes, hence warranting its own category in order to capture this unique concept.

It is difficult to study the impact of so many factors on fatigue because the series of flights that pilots are scheduled for, known as a trip, can include factors that make data aggregation difficult without an enormous sample size. As a result, it is necessary to collect data on targeted operations in order to evaluate the impact of the most disruptive factors on fatigue. Hence, our primary aim is to compare sleep, sleepiness, performance, and workload during trips *with* circadian disruption to trips *without* circadian disruption. We will collect observational data on the other factors that were identified in the focus groups in order to help inform future research in those areas. We will study participants during their normal scheduled operations.

6. Why Human Research is Required

Human research is required because there are no other reliable, efficient, and cost-effective methods for obtaining such information from animal or modeling sources. Only performance by humans is possible or relevant.

7. Conflict of Interest

Do any of the participating study investigators or other research personnel (or their immediate family/significant other) have a financial and/or intellectual property interest in the sponsor or products used with this project?

____Yes __X__No

8. Plan of Study

8.1 Protocol Overview

Scientific Merit. Please see attached ARC476 for scientific review and approval.

Specific Aims. The goal of this study is to provide insight into the influence of trips including circadian disruption on pilot cognitive performance, fatigue, sleepiness, sleep, and workload during short-haul operations across multiple airlines.

Hypotheses.

We aim to study pilots completing trips that include circadian disruption compared to trips that do not include circadian disruption.

- We hypothesize that cognitive performance, fatigue, sleepiness, and sleep outcomes will be worse during circadian disrupted trips compared to trips that do not involve circadian disruption.

Primary Outcome Measures.

Objective cognitive performance will be measured by the **psychomotor vigilance task (PVT)**, a simple reaction time task with outcome measures including mean reaction time, response speed (1/reaction time) and number of lapses (reaction time >500 ms). PVT performance will be measured at, or near, the timing of top of descent (TOD) during each flight.

Statistical Analyses.

The following factors will be also considered for inclusion in the analysis:
- **Schedule features:** flight duration, duty duration, duty start and finish times
- **Individual factors:** age, experience, chronotype (as measured by the morningness-eveningness questionnaire), sleep need
- **Sleep:** sleep duration, sleep loss, sleep start and finish times (all measured by the actiwatch)
- **Fatigue/alertness:** pre- and post-sleep and on-duty fatigue and alertness ratings (as measured by subjective scales)
- **Workload:** hassle factors encountered during flights and NASA TLX

8.2 Equipment

The study will involve evaluating pilot sleep, sleepiness, performance, and workload among on-duty pilots. All devices are commercial, off-the-shelf products with no modifications and used as directed.

iPod. Participants will be issued an iPod Touch with a pre-loaded application (NASA PVT+) which includes a sleep diary, cognitive tests, and subjective scales (Figure 1). Using the NASA PVT+ App, measures will include PVT speed (1/reaction time) and lapses conducted at pre-flight, top of descent (TOD), post-flight, and on days off. Subjective fatigue ratings using the Samn-Perelli 7-point scale and sleepiness ratings using the 9-point Karolinska Sleepiness Scale at pre-flight, TOD, post-flight, and on days off will also be reported. At the end of each flight, participants will complete the NASA-TLX, hassle factors, and information about any fatigue countermeasures that they used. They will also capture information about the characteristics of the flight at the end of each Flight Duty Period (FDP). Prior to and at the end of the study, they will use the app to complete baseline questionnaires.

Actigraphy. Participants will wear a small wristwatch-like device (Actiwatch, Philips Respironics, Murrysville, PA, USA) on the wrist of their non-dominant arm (Figure 2). The actiwatch will be worn continuously throughout the study period including on days off. Actigraphy uses accelerometry and a light sensor to determine sleep and wake patterns and may be worn for several weeks at a time. It will provide us with objective sleep measures which can be compared and correlated with other measures recorded in the NASA PVT+ App.

Light and Temperature Sensor. Participants will wear a small (~1 square inch) light sensor clipped to their clothing in order to assess their lighting and ambient temperature exposure. This device can be placed on a bedside table during sleep. It can record light information for several weeks and does not require the user to interact with it in any way. The data obtained from this sensor will allow us to use the participant's pattern of light exposure to estimate circadian phase using a biomathematical model (Mohamed et al., 2021).

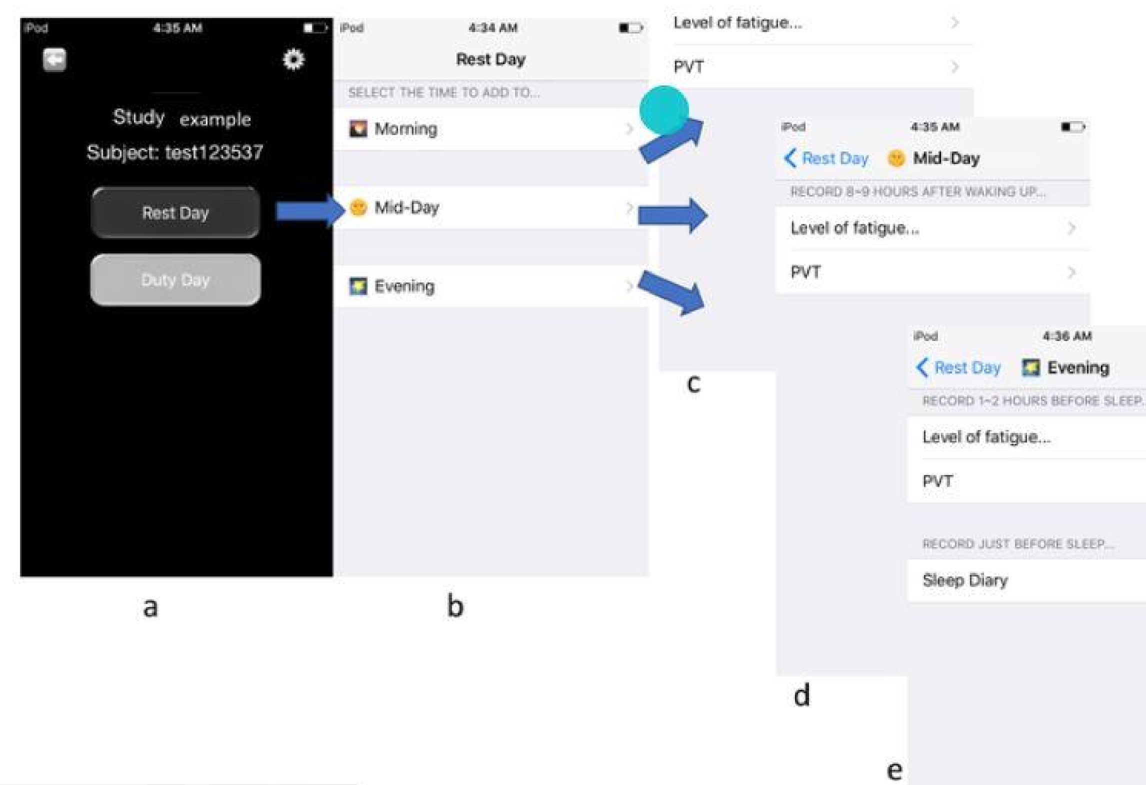

Figure 1. NASA PVT+ App screenshots

Figure 2. Actiwatch Spectrum Device

8.3 Stimuli

None

8.4 Prior to Runs

Recruitment material will be disseminated via company email and safety newsletters.

Interested participants will be asked to contact a research coordinator to confirm their interest and eligibility. If the participant is interested and eligible, the research coordinator will send a copy of the consent form via email for the participant to review and then schedule a time at least 24 hours later for a designated member of the research team to review the informed consent and study procedures with the participant. Informed consent will be completed by the principal investigator or a designated member of the study staff. As pilots could be based in many locations across the country, informed consent will be completed either by phone, video conference, or in person. If the informed consent session is not conducted in-person, DocuSign will be used to obtain the participant's signature and an electronic copy of the signed consent will be emailed to the participant. If the informed consent session is conducted in-person, a paper copy with wet ink signature may be collected and a photocopy will be given to the participant.

8.5 Experiment Design

We will collect objective and subjective sleep, sleepiness, workload, and performance data from on-duty pilots during the aforementioned short-haul flight operations. Data will be collected during days off prior to the trip start, during flights, and during days off following the flight operations. Each pilot will collect data during at least two trips.

8.6 Data Protection

Types of Data. Several questionnaires and PVT tests will be collected using the iPod app. All of the questionnaires are included in the supplemental material submitted with this protocol. We will not collect any personally identifying information using the app. We will collect the participant's name, e-mail address, phone number, and preferred mailing address solely for the purposes of conducting the study (i.e., to coordinate mailing the study devices and to provide compensation, if applicable).

Data Management/Storage. To ensure that individual crew data remains confidential, participants will be allocated an individual numerical code. All data will be collected using this code and not the individual's name or other identifiable information. The data sheet linking names and codes will be stored on an encrypted hard drive following NASA IT security rules.

Coded study data will be stored on devices provided by each airline and/or their research partner (Delta Airlines partners with Dr. Barger at Brigham and Women's Hospital; United Airlines partners with Dr. Lamp at Washington State University). Coded data from all airlines will be archived and aggregated at Washington State University for processing and analysis. Data access will be limited to personnel named on this protocol. NASA researchers will access study data either via computers provided by the airlines or their research partners or via encrypted VPN. The results of the research will not be presented in any form that identifies individuals.

The data will not be used to make employment measures or decisions with respect to individuals.

Participant Withdrawal. Participants who choose to withdraw their consent may do so at any time. Any partial data that has been collected will be considered for analysis unless the participant requests that their data be deleted.

9. Proposed Test Schedule

The study will take place over an estimated one-year period. Each participant will collect data during two trips lasting 2-7 days each, with up to 3 days of off-duty data collection before and after each trip, for a total data collection of up to 26 days per pilot.

Pre-study Questionnaires

Once consented, participants will be provided with instructions regarding the study procedures and equipment (i.e., an iPod with the NASA PVT+ application, an Actiwatch, and a light and temperature sensor). Equipment will be either be mailed to the participant or available for collection from a designated staff member. Participants will then complete a series of baseline questionnaires including a demographic questionnaire, performance questionnaires, a baseline exercise questionnaire, the Morningness/Eveningness Questionnaire (MEQ), the Epworth Sleepiness Scale (ESS), the Pittsburgh Sleep Quality Index (PSQI), the Insomnia Severity Index (ISI), and the NASA Task Load Index (TLX), using the NASA PVT+ app. Participants will also complete a practice sleep diary and a practice PVT in order to ensure that they understand the study procedures. Demographic information, including age, flight experience, living arrangements, and the results of the aforementioned questionnaires will be used as covariates in data analysis as each of these factors can influence sleep and performance.

Procedure

Participants will begin data collection 1-3 days prior to their trip departure (depending on the participant's availability and off-duty time between trips). Data will be collected using the NASA PVT+ App and the Actiwatch. Participants will begin wearing the Actiwatch and continue to wear it for the duration of the study period which will conclude up to 3 days following their return from their trip. They will make entries in the App reporting on their sleep periods at the beginning and end of each day, including days off. Participants will also have additional entries during flight duty periods.

A study staff member will check in (e.g., via phone call) regularly to remind the participant to complete the study tasks and to answer any additional questions.

Details are outlined below as well as summarized in Table 2 and Figure 3. Full details can be found in supplemental documents.

Return of equipment. Participants will be provided with either a return pre-paid box or instructions on where to return the equipment to a designated staff member. Data will be downloaded, cleared, and a study ID reset on each device before sending to another participant. Data collected on iPod and actiwatch devices will only be identified by an ID code. No identifying information will be collected during the study period.

Morning Sleep Diary. At the beginning of each day, participants will complete a sleep diary within the NASA PVT+ App. Each entry will include: wake-up time, a rating of sleep quality (5 -point scale from Extremely Good to Extremely Poor), the Samn-Perelli (SP) and Karolinska Sleepiness Scale (KSS), the location of their sleep, the timing and duration of any awakenings during the sleep period, and any additional information (i.e., notes).

Evening Sleep Diary. At the end of each day (right before sleep), participants will use the App to report the time they are going to sleep, the location of their sleep (e.g., home, hotel), if they used any caffeine during the day (amount used), any naps during the day (including timing and duration), timing/type of meals, and timing/type of exercise. Participants will also complete the SP and KSS and have an opportunity to provide any additional information about the day if necessary.

Flight Duty Period Data Collection. On flight duty days, participants will have additional entries and tasks to complete within the NASA PVT+ App (i.e., pre-duty, during flight, post-flight, and post-duty). Pre-duty entries will include: flight information, layover information, commute information, caffeine intake, the SP and KSS, and the Psychomotor Vigilance Task (PVT). During their flight, they will complete the SP, KSS, and the PVT, at or near the timing of TOD. Post-flight entries will occur within one hour of landing and will include flight information, the NASA TLX, report of fatigue countermeasures used, and hassle factors experienced (e.g., weather, air traffic control issues, traffic), SP, KSS, and PVT (if needed). Post-duty entries will include: duty information, operational factors (e.g., delays, sit times), overall fatigue rating (visual analog scale), KSS, SP, and PVT. Participants will also complete both the morning and evening sleep diary entries on flight duty days. Additional questions in the evening sleep diary on duty days include: commute information (i.e., timing, duration, and type of travel).

Table 2. Timing of data collection (repeated for one circadian-disruption trip and one trip without circadian disruption)

	1-3 Off-duty Days	Each Day of the Trip	1-3 Off-duty Days
Morn/evening Sleep Diary	✓	✓	✓
Sleepiness/ Fatigue	✓	✓	✓
Performance	✓	✓	✓
Workload		✓	
Duty information		✓	

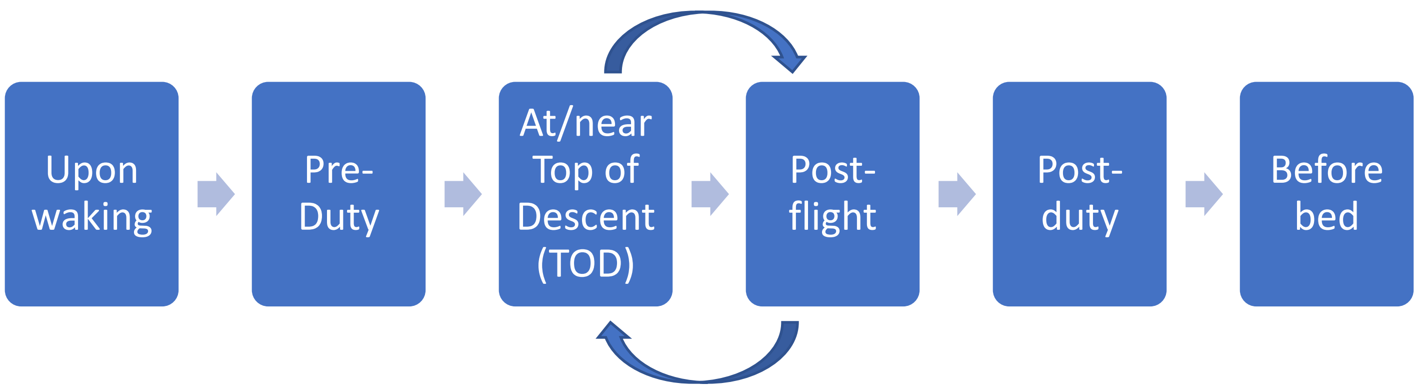

Figure 3. Timing of flight day data collection

Tests and Scales

Morningness/Eveningness Questionnaire (MEQ). The MEQ is a widely used self-assessment questionnaire (19 items) designed to determine a person's chronotype, that is, whether they experience peak alertness in the morning, evening, or in between.

Pittsburgh Sleep Quality Index (PSQI). The PSQI is used to measure sleep quality in adults over the last month. The scale is broken down into 7 Components, which include: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction. Higher scores indicate poorer sleep quality.

Insomnia Severity Index (ISI). The ISI is a 7-item questionnaire used to assess the severity of daytime and nighttime components of insomnia. The scale uses a 5-point Likert scale to measure the different components, including: severity sleep onset, sleep maintenance, early morning awakening problems, sleep dissatisfaction, interference of sleep difficulties with daytime function, noticeability of sleep problems by others, and distress caused by the sleep difficulties. Total score can range from 0-28 with higher scores indicating more severe insomnia.

Epworth Sleepiness Scale (ESS). The ESS is a routinely used self-administered questionnaire (8 items) that can be used to assess daytime sleepiness.

NASA-TLX. The NASA Task Load Index (TLX) is a subjective, multidimensional tool that rates workload relative to a task. The TLX is taken at the start of the study to make a series of pairwise comparisons and then again for rating each flight period.

Hassle Factors. Factors that may affect workload during flight operations (e.g., weather, air traffic control (ATC), cabin activity, procedures & documentation) will be reported for each flight period.

Samn-Perelli Scale (SP). The Samn-Perelli Scale is a commonly used 7-point scale for self-rating levels of fatigue at a given time. The scale includes: 1= fully alert – wide awake, 2= very lively, 3= okay - somewhat fresh, 4= a little tired, 5= moderately tired, 6= extremely tired, 7= completely exhausted.

Karolinska Sleepiness Scale (KSS). The KSS is a widely used 9-point scale for self-rating levels of sleepiness at a given time. The scale includes: 1 = extremely alert, 2= very alert, 3 = alert, 4= rather alert, 5 = neither alert nor sleepy, 6= some signs of sleepiness, 7 = sleepy – but no difficulty remaining awake, 8= sleepy – some effort to keep awake, and 9 = extremely sleepy – fighting sleep.

Sleep Quality rating. All sleep periods (including naps) will be rated for quality. The scale includes: 1 = extremely good, 2= good, 3 = average, 4= poor, 5 = extremely poor.

Psychomotor vigilance task (PVT). The PVT is a widely used sustained-attention, reaction-time task that measures the speed with which subjects respond to a visual stimulus. The PVT is a simple task where the subject taps the screen as soon as a visual stimulus appears. The stimulus appears randomly every few seconds during the 5-minute task.

The initial screen orients the subject to take the test in landscape mode with thumbs hovering over the screen for response (Figure 4).

Figure 4. Orientation screen shown prior to each PVT

At random intervals the counter starts running with the clock showing in the response box (Figure 5). Tapping the screen stops the counter, showing the reaction time, before the screen clears and readies for the next stimulus presentation. At the end of the test the screen will display DONE.

Figure 5. PVT screen showing response time (ms)

10. Practical Aspects of Safety and Ethical Conduct

This study is a minimal risk study. The risks associated with the protocol may differ from normal flying duties due to potential discomfort and inconvenience with wearing the actiwatch and completing tests with the PVT+ App. All participants are active-duty pilots with the appropriate clearances for flight duties. The actiwatch and iPod device housing the NASA PVT+ App are commercially available products. Participants will be informed that they may skip tests or stop the study at any time if they feel that their participation compromises flight safety. Given that the risks associated with this study are minimal, medical monitoring is not required.

11. Number, Source, and Pertinent Characteristics of Participants

Study Population. The study population does not include astronauts. All subjects will be medically qualified, active-duty flight crewmembers. Current American Airlines, United Airlines, Delta Airlines, and Southwest Airline pilots are eligible to participate in the study (pending review of other inclusion criteria, see below).

Participant Recruitment. Members of fatigue risk management teams and union representatives across each airline will distribute recruitment material via e-mail and in safety newsletters to short-haul flight crew. When feasible, members of the study team may set up study information tables in the crew rooms at airports. Participation will be completely voluntary.

Participants will not be excluded based on race, ethnicity, or gender.

Sample Size. Based on previous studies in similar studies of chronic sleep loss compared to rested performance, we expect that the effect size for PVT lapses using a 5-minute PVT will be approximately 0.75. When accounting for the clustered nature of the study (i.e., four airlines), we estimate the inter-class correlation adjustment to be .015. As such, with an alpha level of 0.05 and 80% power, we estimate that we need 18 participants per condition (night flying or circadian switches), per airline for a total sample size of 36 participants per airline. In order to account for attrition after consent, unplanned schedule changes, and incomplete data collection, we would like to recruit up to an additional 15 participants per airline. This would result in a total sample size of 204 pilots.

Inclusion/Exclusion Criteria. All medically qualified, active-duty pilots currently flying short-haul operations are eligible to be included as participants in the study. Participants must be line pilots that spend at least 50% of their typical monthly schedule flying short-haul operations (defined at flights under 6 hours duration).

All flight crew who fly short-haul operations that meet the following study inclusion criteria will be eligible for participation.

Participants must be scheduled for and willing to collect data on each of the following:

a. <u>Trip *with* Circadian Disruption</u>: A trip containing one of the following types of WOCL infringement:

i. *Overnight FDPs*. An FDP in which the pilot is operating one or more flights through the WOCL (0200-0559h) relative to the pilot's home-base time or clock time.

OR

ii. *Circadian Switching*. At least one FDP that starts between 0000-0659h relative to home-base time, followed by at least one FDP that ends between 0000-0659h, or *vice versa*, within the same trip (e.g., an FDP that begins at 0500h and the next FDP ends at 0100h or *vice versa*).

AND

b. <u>Trip *without* Circadian Disruption</u>: This trip must not contain any duties that are scheduled to begin or end between 0000h and 0659h relative to home-base time.

Proposed Test Schedule. Pending final decisions by the airlines regarding flights to be studied, the study is expected to commence in the summer of 2022.

12. Benefits of Participation

The results of this study may inform our understanding of how fatigue emerges during typical short-haul operations in the United States.

13. Possible Inconveniences, Discomfort, Pain, and Risks to the Participants

The risks associated with the protocol may differ from normal flying duties as follows:

It is possible that crew could experience slight discomfort and inconvenience from wearing an Actiwatch such as skin irritation or a rash, although no more than from wearing a wristwatch. An Actiwatch is the size of a wristwatch and is designed to be worn for weeks at a time.

Participants will record their performance using a handheld device employing the data collection app. Some crew could experience a degree of discomfort and inconvenience as the result of having their performance recorded for an extended period. Participants could be distracted from their flight duties while taking the tests, however, they will be instructed to take the test prior to the TOD, while still in the cruise phase when distractions are minimal.

Participants may also be inconvenienced by having to complete sleep, fatigue, and workload ratings. However, it is estimated that study information will only take about a total of 30 min in a day to record, with each phase of collection (e.g., pre-duty, evening diary) taking no more than 7 minutes.

As the study data will be archived at each airline or airline partner, it is possible that individual ID-coded data could be viewed or used by airline personnel.

14. Measures Taken to Minimize Discomfort and Risks

If the participant finds the actiwatch uncomfortable, then the study staff will work with the participant to determine if a different band could be used to minimize discomfort. If no acceptable alternatives are identified, then the participant will be free to discontinue wearing the device, which may require withdrawal from the study.

Participants will also be instructed to stop taking the PVT if they need to attend to their flying duties.

Participants will be informed that they are free to withdraw from the study at any time if they find the daily sleep logs and questionnaires too burdensome.

Participants will be informed that their coded data will be stored at their airline and at Washington State University. Only coded data will be archived with each airline in order to minimize the possibility that an individual’s name could be linked to their data.

15. Conditions of Withdrawal from the Experiment

Participation is voluntary and pilots may choose not to participate in all or part of the study and can withdraw at any stage without being penalized or disadvantaged in any way.

16. Remuneration for Participants

All participants will be provided with NASA stickers, patches, mugs, or similar items as a token of appreciation for participation.

Compensation will be provided to participants according to the established rate for similar studies at each airline (if any).

17. Compensation in the Event of Injury

In the event of injury or illness resulting from this study and calling for immediate action or attention, NASA will provide, or cause to be provided, the necessary treatment. If eligible for California Workers’ Compensation benefits while participating in this study, participants cannot sue their employer because the law makes Workers’ Compensation their only remedy against their employer. Participants may have other remedies against other persons or organizations, depending on the circumstances of the injury. NASA will pay for any claims of injury, loss of life or property damage to the extent required by Federal Employees Compensation Act or the Federal Tort Claims Act.

Insurance or medical support that is normally provided to all air crew under company policy provisions at each airline will apply for study participants.

18. Consent Process

Members of fatigue risk management teams and union representatives across each airline will distribute recruitment material via e-mail and in safety newsletters to short-haul flight crew. When feasible, members of the study team may set up study information tables in the crew rooms at airports. Participation will be completely voluntary.

Interested participants will be asked to contact a research coordinator to confirm their interest and eligibility. If the participant is interested and eligible, the research coordinator will send a copy of the consent form via email for the participant to review and then schedule a time at least 24 hours later for a designated member of the research team to review the informed consent and study procedures with the participant. Informed consent will be completed by the principal investigator or a designated member of the study staff. As pilots could be based in many locations across the country, informed consent will be completed either by phone, video conference, or in person. If the informed consent session is not conducted in-person, DocuSign will be used to obtain the participant's signature and an electronic copy of the signed consent will be emailed to the participant. If the informed consent session is conducted in-person, a paper copy with wet ink signature may be collected and a photocopy will be given to the participant.

Participants may choose to withdraw from the study at any stage without being penalized or disadvantaged in any way. Participants will be told to contact the study staff if they wish to withdraw from the study. The study staff will make arrangements to collect the study equipment from the participant at their earliest convenience.

19. References

Bourgeois-Bougrine, S., Carbon, P., Gounelle, C., Mollard, R., & Coblentz, A. (2003). Perceived fatigue for short-and long-haul flights: a survey of 739 airline pilots. *Aviation, Space, and Environmental Medicine*, *74*(10), 1072-1077.

Caldwell, J.A., Mallis, M.M., Colletti, L.M., Oyung, R.L., Brandt, S.L., Arsintescu, L., DeRoshia, C.W., Reduta-Rojas, D.D. and Chapman, P.M. (2006). *The Effects of Ultra-Long-Range Flights on the Alertness and Performance of Aviators* (Report No. TH-066). Ames Research Center. https://ntrs.nasa.gov/citations/20060024526

Flight and Duty Limitations and Rest Requirements: Flightcrew Members, 14 C.F.R. § 117 (2012).

Flynn-Evans, E. E., Arsintescu, L., Gregory, K., Mulligan, J., Nowinski, J., & Feary, M. (2018). Sleep and neurobehavioral performance vary by work start time during non-traditional day shifts. *Sleep Health*, *4*(5), 476-484.

Gander, P. H., Gregory, K. B., Graeber, R. C., Connell, L. J., Miller, D. L., & Rosekind, M. R. (1998). Flight crew fatigue II: Short-haul fixed-wing air transport operations. *Aviation, Space, and Environmental Medicine*, *69*(9, Sec 2), B8-B15.

Honn, K. A., Satterfield, B. C., McCauley, P., Caldwell, J. L., & Van Dongen, H. P. (2016). Fatiguing effect of multiple take-offs and landings in regional airline operations. *Accident Analysis & Prevention*, *86*, 199-208.

Mohamed, A., Kalavally, V., Cain, S. W., Phillips, A. J., McGlashan, E. M., & Tan, C. P. (2021). Wearable light spectral sensor optimized for measuring daily α-opic light exposure. *Optics Express*, *29*(17), 27612-27627.

Powell, D., Spencer, M. B., Holland, D., Broadbent, E., & Petrie, K. J. (2007). Pilot fatigue in short-haul operations: Effects of number of sectors, duty length, and time of day. *Aviation, Space, and Environmental Medicine*, *78*(7), 698-701.

Roach, G. D., Sargent, C., Darwent, D., & Dawson, D. (2012). Duty periods with early start times restrict the amount of sleep obtained by short-haul airline pilots. *Accident Analysis & Prevention*, *45*, 22-26.

Rosekind, M. R., Gander, P. H., Miller, D. L., Gregory, K. B., Smith, R. M., Weldon, K. J., ... & Lebacqz, J. V. (1994). Fatigue in operational settings: Examples from the aviation environment. *Human Factors*, *36*(2), 327-338.

Samel, A., Wegmann, H. M., & Vejvoda, M. (1997). Aircrew fatigue in long-haul operations. *Accident Analysis & Prevention*, *29*(4), 439-452.

Scientific Principles for Fatigue Management. Fatigue Risk Management Systems: Implementation Guide for Operators. Washington, D.C.: International Air Transport Association (IATA), International Federation of Airline Pilots' Associations (IFALPA), and International Civil Aviation Organization (ICAO), 2015.

Vejvoda, M., Elmenhorst, E. M., Pennig, S., Plath, G., Maass, H., Tritschler, K., ... & Aeschbach, D. (2014). Significance of time awake for predicting pilots' fatigue on short-haul flights: Implications for flight duty time regulations. *Journal of Sleep Research*, *23*(5), 564-567.