

Study on the Use of Broadband Sounds to Mitigate Sleep Disruption due to Aircraft Noise

Project 86

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October 25-27, 2022
Alexandria, VA

This research was funded by the U.S. Federal Aviation Administration Office of Environment and Energy through ASCENT, the FAA Center of Excellence for Alternative Jet Fuels and the Environment, project 86 through FAA Award Number 13-C-AJFE-UPENN under the supervision of Susumu Shirayama. Any opinions, findings, conclusions or recommendations expressed in this material are those of the authors and do not necessarily reflect the views of the FAA.



- Sleep disturbance is considered one of the most detrimental effects of aircraft noise exposure.
- People exposed to aircraft noise may not be eligible for sound insulation or their sleep may still be affected by aircraft noise despite sound insulation measures.
- Low-cost yet effective mitigation measures are needed to prevent aircraft noise-induced sleep disturbance.
- The main goal of this study is to investigate the effectiveness of broadband noise (BN) and earplugs (EP) to mitigate the sleep-disturbing effects of different kinds of aircraft noise.

- Millions of people use broadband noise (e.g., white noise machines, YouTube videos) to promote sleep, even in the bedroom of newborns and toddlers.
- Yet, according to our own systematic review of the literature neither the safety nor the effectiveness to reduce sleep have been demonstrated.
- How broadband noise could promote sleep:
 - Masks sounds intruding into the bedroom
 - Promotes sleep (i.e., “lulls” the brain into sleep)
 - Becomes part of a sleep ritual (i.e., stimulus control)
- How broadband noise could harm sleep and health:
 - It disturbs sleep itself.
 - It masks meaningful sounds (e.g., fire alarm, crying baby).
 - It induces noise-induced hearing loss.

- Sleep laboratory study in the hospital of the University of Pennsylvania
 - Has four separate acoustically isolated bedrooms that will be acoustically calibrated
 - Broadband noise will be played back over ceiling speakers (JBL Control 47LP) and aircraft noise via high quality active studio monitors (Neumann KH 310 A)
- Twenty-four subjects will be investigated in groups of 4 over 7 consecutive nights
 - Powered to detect relevant (0.6 SD) change in Deep+REM sleep with >80% probability.
 - Subjects will arrive in the lab at 8 pm, are scheduled to sleep between 11 pm and 7 am and will leave the sleep laboratory in the morning to go about their normal lives (no naps and no caffeine allowed after 3 pm).
 - Plan to have one back-up subject per run plus one back-up run

Exclusion Criteria

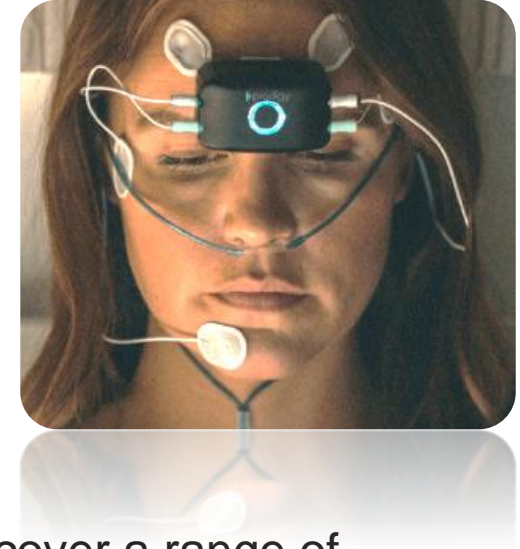
- Age < 21 years or > 50 years
- Hearing loss > 25 dB in any frequency band up to 8 kHz
- History of neurological, psychiatric, or other medical condition that excludes participation.
- Current mania or psychosis.
- Current depression as determined by the Beck Depression Inventory (Beck, 1996).
- Alcohol or drug abuse in the past year based upon history and urine toxicology screen.
- Excessive alcohol intake (≥ 21 drinks per week) or binge alcohol consumption (> 5 drinks per day).
- Excessive caffeine consumption (> 650mg/day combining all caffeinated drinks regularly absorbed during the day).
- Current smoker/tobacco user or using nicotine replacement therapy. Those that have been nicotine-free for ≥ 30 days will be included.
- Body Mass Index ≥ 35 .
- Acute, chronic, or debilitating medical conditions, major Axis I psychiatric illness based on history, physical exam, blood and urine chemistries, and CBC.
- Individuals who self-report a history of recurrent seizures or epilepsy or have a history of medical conditions that could increase the chance of seizures (e.g., stroke, aneurysm, brain surgery, structural brain lesion).
- Cardiovascular, neurological, gastrointestinal, or musculoskeletal problems that exclude participation.
- Major controlled or uncontrolled medical condition such as congestive heart failure, neuromuscular disease, renal failure, cancer, COPD, respiratory failure or insufficiency, cardiac arrhythmia, or patients requiring oxygen therapy (as determined by self-report).
- Currently working night, swing, split or rotating shift.
- Current use or use of within the past month of a prescription or over-the-counter sleep medication or stimulant; use of psychoactive medication (based on self-report and review with a study clinician).
- Pregnant or currently breast feeding
- Prior history or diagnosis of any sleep disorder including Obstructive Sleep Apnea (AHI ≥ 15 events/hour) – from ambulatory or in lab polysomnography; Restless legs syndrome or periodic limb movement disorder; Insomnia; Parasomnia; High Risk of OSA based on STOP-BANG Questionnaire (“yes” on at least 4 of 8 questions); High Risk of Restless Legs Syndrome (RLS) based on Cambridge-Hopkins Screening questionnaire; High Risk of Insomnia based on Insomnia Severity Index (score of 22 or higher)
- Individuals who self-report severe contact dermatitis or allergy to bandages, silicone, nickel or silver.
- Planned travel across more than one time zone one month prior to and/or during the anticipated period of the study.
- Intentional naps during the week.
- Positive Covid-19 test at pre-screening

→ Healthy individuals

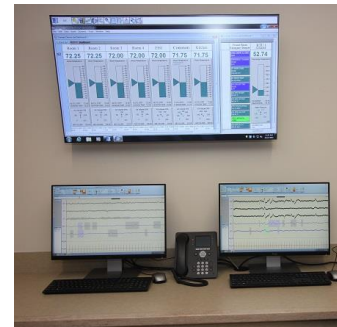
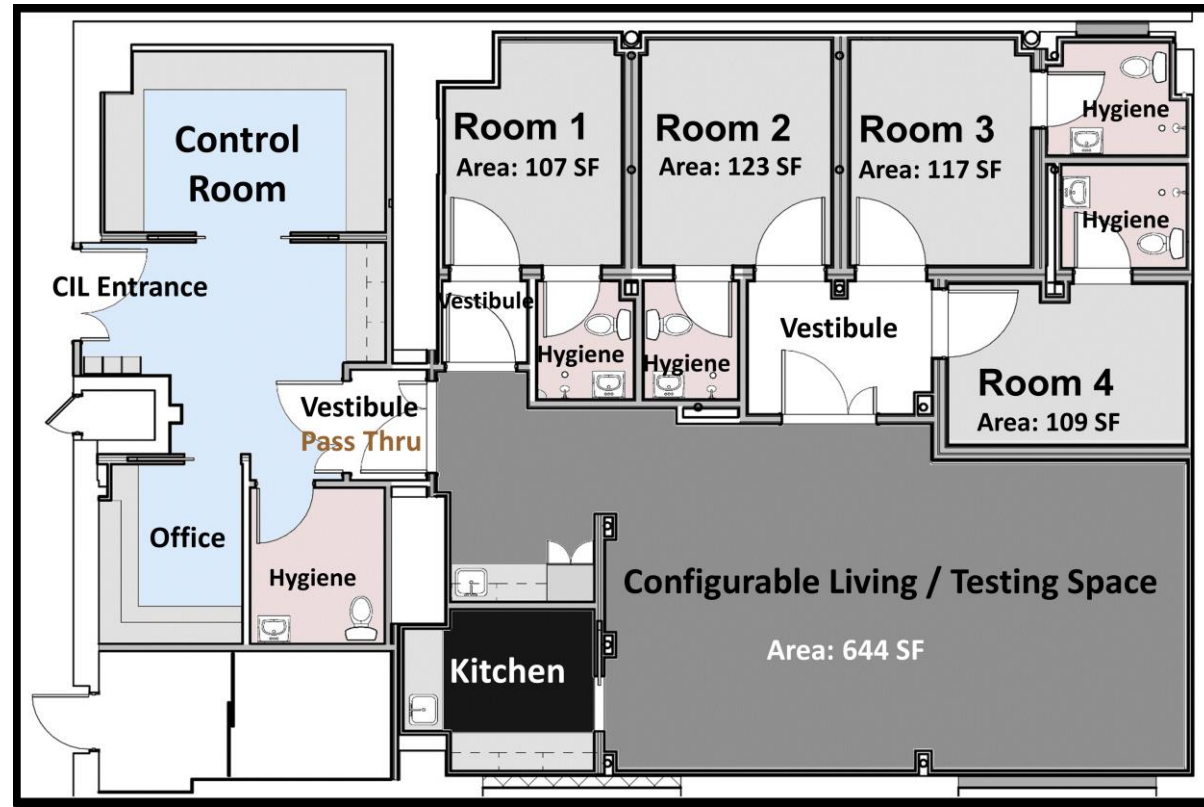
Measurements

- During sleep:
 - Polysomnography: Electroencephalography (EEG), Electrooculography (EOG) and Electromyography (EMG)
 - Electrocardiogram plus body movements with Faros 180 device
 - Sounds and sound level in bedroom
- Before and after sleep:
 - Cognition test battery
 - Computerized battery of 10 cognitive tests that cover a range of cognitive domains
 - Driving simulator task
 - Pure-tone audiometry (aka hearing test)
 - Surveys on sleepiness, mood states, stress
 - Blood draw for RNA expression analysis (morning only; CAMI)
- 24/7:
 - Wrist actigraphy

Prodigy Sleep System



Chronobiology and Isolation Laboratory



Conditions

- After an adaptation night, participant will be exposed to one of the following conditions in the following 6 nights:
 - **CTRL**: Control night without any noise exposure and without earplugs
 - **AN**: Aircraft noise only
 - **BN50**: Broadband noise 50 dBA only
 - **AN+EP**: Aircraft noise plus earplugs
 - **AN+BN40**: Aircraft noise plus broadband noise 40 dBA
 - **AN+BN50**: Aircraft noise plus broadband noise 50 dBA
- Conditions are randomized and balanced
 - Each condition in each position exactly once
 - Each condition preceded by each other condition exactly once

Group	Night 1	Night 2	Night 3	Night 4	Night 5	Night 6	Night 7
1	Adaptation	A	B	C	D	E	F
2	Adaptation	B	D	A	F	C	E
3	Adaptation	C	A	E	B	F	D
4	Adaptation	D	F	B	E	A	C
5	Adaptation	E	C	F	A	D	B
6	Adaptation	F	E	D	C	B	A

- The Aircraft Noise night consists of 120 noise events of the following categories:
 - Jet noise (from 2004-2006 DLR AIRORA study)
 - Helicopter noise
 - Drone noise
 - Low sonic boom noise
 - Meaningful sounds (alarm, baby crying)
- Representative events will be chosen for each category.
- Noise events with maximum sound pressure levels of 45, 50, 55, 60 and 65 dBA at the sleeper's ear will be played back at random but balanced intervals.
- Individual events will be repeatedly played back to facilitate averaging within and across participants.

- Whole Night
 - AN disturbs sleep and reduces time spent in SWS+REM sleep.
AN vs. CTRL
 - BN mitigates the negative effects of AN in a dose-dependent fashion.
AN+BN50 vs. AN+BN40 vs. AN
 - Earplugs mitigate the negative effects of AN.
AN+EP vs. AN
 - BN promotes sleep.
BN50 vs. CTRL
- Event-related
 - Different types of AN differ in their awakening potential.
 - The masking effects of BN differ by AN type.
 - BN masks meaningful sounds (i.e., alarm, baby crying).

Schedule and Status



Start date: 10/1/2022 (tentative)

Milestone	Planned Due Date
IRB approval obtained	12/1/2022
PSG system and hearing assessment device acquired and procedures established	1/1/2023
Aviation noise events received from FAA	2/1/2023
Acoustic setup of sleep laboratory completed	4/1/2023
Measurement campaigns 1-3 completed	10/1/2023
Measurement campaigns 4-6 completed	4/1/2024
Data analysis completed, final report written	9/30/2024

Acknowledgements



- Susumu Shirayama and Sean Doyle (FAA)
- Christopher Hobbs (FAA)

Participants

- Christopher Jones, Michele Carlin, Sierra Park-Chavar, Marc Kaizi-Lutu, Victoria Schneller, Yoni Gilad, Haochang Shou, Quy Cao (UPenn)
- Hilary Uyhelji (FAA CAMI)
- Daniel Aeschbach (DLR)
- Michael Smith, University of Gothenburg