National Sleep Study Overview

ASCENT Advisory Committee Meeting 4/6/2022

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Background

- Field studies are needed to acquire current U.S. data on sleep disturbance relative to varying degrees of aircraft noise exposure to inform any potential policy considerations.

- An inexpensive methodology of using actigraphy and electrocardiography (ECG) has previously been found to provide a sensitive measure of awakenings.

- In ASCENT 017, we established the feasibility of having study participants complete unattended ECG and actigraphy measurements in two pilot studies near Philadelphia and Atlanta Airport.

- The two pilot studies were used to adjust the design of and perform power calculations for the National Sleep Study.

Approach-In Home Study

- – Equipment is mailed to participant's homes

- – An instruction manual and videos are provided on how to use the equipment

- – Physiological Monitoring: 2 cable (1 channel) ECG (250 Hz) and body movements (25 Hz)

- – Sound recording equipment: Portable audio recorder with class 1 microphone

- – Total equipment cost for 1 setup ~$1500

- – Participants take part for 5 nights (Mo-Fri)

- – Staff are available 24/7 by cell-phone to answer questions

Study Design Considerations

- We used simulations to determine the necessary sample size. Simulations were based on:

    - Traffic at 111 major US airports with at least one runway with on average ≥ 1 flight per hour in the period 10 pm to 7 am (2018 traffic data)

    - Previous field studies around Philadelphia, Atlanta, Cologne and Frankfurt airport (282 participants, 29,714 aircraft noise events)

- Primary Outcome

    - Exposure-response function that describes the relationship between the <u>maximum sound pressure level of an aircraft overflight</u> (measured inside the bedroom) and the <u>probability to wake up</u> (inferred from changes in heart rate and body movements).

    - We will also investigate this and other secondary outcomes in relation to long-term average noise metrics (DNL and average nighttime noise level L_{night}).

Study Design Considerations

- A priori set criterion:
  Half-width of 1.5% for the 95% confidence interval of the exposure-response function at maximum sound pressure level of 50 dB (Q3)

- Simulated data were reduced by a randomly selected 30% and randomly selected 5% participants were deleted to account for potential missing data.
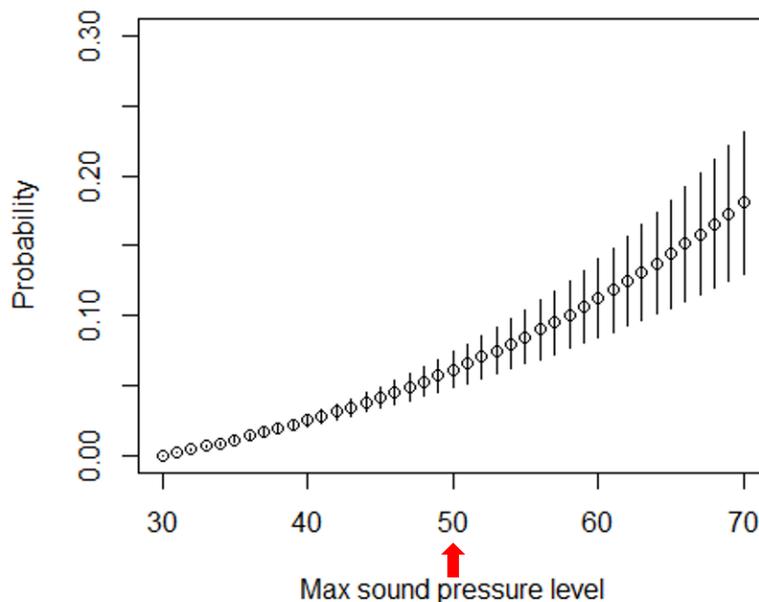
Simulated exposure-response function for N=400 subjects

Final Study Design

- We are sampling individuals from 202 Runway Groups at 77 airports.

- We are using <u>stratified random population sampling</u>, so that the sample will be generalizable to populations most affected by aircraft noise.

  – Sampling regions are classified into 40<45 dB, 45<50 dB, 50<55 dB and ≥55 dB based on L_{night}.

  – Within these four strata, households are sampled proportionately to the number of households affected across all 77 airports with at least one medium to high traffic Runway Group.

- We will investigate a total of <u>N=400 participants</u> over a period of 2 consecutive years.

Covid-19 Considerations

Traffic Scenario (relative to 2018 traffic)	Sample Size			
	400	450	500	550
100% traffic	0.0143	0.0134	0.0129	0.0120
20% reduced traffic	0.0144	0.0139	0.0129	0.0130
30% reduced traffic	0.0148	0.0143	0.0142	0.0128
40% reduced traffic	0.0154	0.0150	0.0140	0.0138
50% reduced traffic	0.0162	0.0153	0.0144	0.0142
60% reduced traffic	0.0166	0.0158	0.0156	0.0151
70% reduced traffic	0.0187	0.0166	0.0164	0.0152
80% reduced traffic	0.0205	0.0186	0.0181	0.0172

Table entries show half-width of 95% confidence interval of the exposure –response function at $L_{AS, max}$ 50 dB (a priori set goal was <0.015).

Actual air traffic volumes will be checked after year 1 of data acquisition and compared to 2018 traffic data:

- Up to 30% reduction → no action necessary

- 30%-40% reduction → increase sample size to 450

- 40%-50% reduction → increase sample size to 500

- >50% reduction → consider suspending study

Optimal Recruitment

Sampling protocol			Surveys sent to receive 1 response (n)*	Surveys sent to recruit 1 participant (n)*#	Costs ($)							
Follow-up waves (n)	Survey length	Survey incentive			Initial wave	Follow-up wave 1	Follow-up wave 2	Follow-up wave 3	Total per mailed individual	Per response received*	Total to receive 1 response†	Recruit 1 participant†#
3	Short	$2	4.6	50.7	3.01	0.70	1.01	1.01	5.74	26.44	28.89	317.51
3	Medium	$2	4.9	53.6	3.09	0.70	1.09	1.09	5.96	29.09	31.84	349.88
0	Long	$2	12.2	134.1	3.09	-	-	-	3.09	37.65	39.54	434.48
3	Long	$2	6.1	67.4	3.09	0.70	1.09	1.09	5.96	36.59	39.99	439.50
2	Long	$2	8.3	91.5	3.09	0.70	1.09	-	4.88	40.64	44.01	483.66
0	Long	Gift card	32.3	354.5	1.09	-	-	-	1.09	40.83‡	46.81‡	503.38

Based on models adjusted for number of follow-up waves, survey length, survey incentive

*Assumes 100% delivery rate

†Assumes 87.6% delivery rate and, if applicable, $0.248 recouped from non-deliverable surveys

‡Includes a mean gift card cost of $5.67

#Assumes 9.1% participation rate from completed surveys across all survey mailing rounds, independent of mailing protocol.

Does not include cost for actual participation in the field study ($150 or $200).

*Smith et al., BMC Medical Research Methodology 19(1): 230, 2019*

Publications

- Basner M, Witte M, McGuire S
"Aircraft Noise Effects on Sleep—Results of a Pilot Study Near Philadelphia International Airport."
International Journal of Environmental Research and Public Health 16(17): 3178, 2019.

- Smith MG, Witte M, Rocha S, Basner M
"Effectiveness of incentives and follow-up on increasing survey response rates and participation in field studies."
BMC Medical Research Methodology 19(1): 230, 2019.

- Rocha S, Smith MG, Witte M, Basner M
"Survey Results of a Pilot Sleep Study Near Atlanta International Airport."
International Journal of Environmental Research and Public Health 16(22): 4321, 2019.

- Smith MG, Rocha S, Witte M, Basner M
"On the feasibility of measuring physiologic and self-reported sleep disturbance by aircraft noise on a national scale: A pilot study around Atlanta airport."
Science of the Total Environment 718: 137368, 2020.

Study Flow Chart

Westat data delivery (weekly)

Monthly mailings (N=1,120)

Interested? — **NO** → File as "Not Interested"

YES

Eligible? — **NO** → Contact respondent to inform that "not eligible" → File as "Ineligible"

UNCLEAR / **YES**

Contact respondent to confirm eligibility

Contact respondent for informed consent

Possible to establish contact? — **NO** → File as "No Contact"

YES

Subject consents?

YES → Schedule in-home study → File as "Enrolled"

NO → File as "Declined"

Study Exclusion Criteria

- Under 21 years of age

- Body mass index (BMI) of >35 or <17 kg/m2, corresponding to classification as Obesity Class II ("severely obese") and moderately underweight respectively (25.2%).

- Diagnosis of a sleep disorder by a heath professional, including but not limited to: (a) sleep apnea, (b) narcolepsy, (c) restless leg syndrome, (d) period limb movement disorder. Insomnia is NOT an exclusion criterion (28.0%).

- Use of medication (either prescribed or "over-the counter") to help sleep three times or more per week, over the past month (28.9%).

- Self-reported or diagnosed problems hearing (27.6%).

- Cardiac arrhythmia (7.3%)

- Overnight shift work, defined as working for at least 4 hours between 00:00 to 06:00 (12.2%).

- Have dependents that frequently require care during the night (15.4%).

- Pregnant

- Already participated in the ATL and PHL pilot studies

  *Participants can present with more than one exclusion criterion.

Approach-In Home Study

National Sleep Study
INSTRUCTION MANUAL

For instructional videos visit:
https://upenn.box.com/v/sleepstudy

Your start date for the measurement is:
Monday, MM/DD/YYYY

During the study if you have any questions or concerns please call: 215-510-6299

Tuesday Evening (Night 2)
Step 1: Starting the Sound Recorder

- ❑ If you have not done so already, turn the sound recorder on by pressing and holding down the power button located on the left hand side of the device. The screen will light up. Leave the sound recorder plugged in and powered on for the entire duration of the study.

  Power button

- ❑ To start recording, press the REC button on the sound recorder (the one with the red dot). The red light next to it will light up.
- • If the red light does not light up, make sure the sound recorder is still powered on. The red light next to 'REC' should remain on while recording.
- • The two indicator lights above '1' and '2' should both be on as well. If they are not both lit, press the '1' button.

  REC Button

- ❑ Check that the counter in the top left corner of the sound recorder screen is increasing in number.
- ❑ Make sure that there is NO battery symbol on the upper right corner of the display screen. If this battery symbol appears it means the AC adapter is NOT plugged in. Make sure to plug the power cord securely into the recorder and securely into the wall outlet or the extension cord.

  Counter

Subject: XXXXXXXX   Page 43

Tuesday Morning Survey (Morning 1)

Instructions
- Please mark all answers clearly
- If the question is multiple choice, mark your answer by placing an x in the box: ☒
- If there are no response alternatives listed, write in your response in the provided space

1. Current date: _____   Current time:_____

2. In the 6 hours before you went to bed did you drink any alcohol?
   ☐ Yes
   ☐ No

3. In the 6 hours before you went to bed did you drink any caffeine (e.g. coffee, tea, soda)
   ☐ Yes
   ☐ No

4. Thinking about yesterday, how stressful was your day?

☐	☐	☐	☐	☐
Not at all	Slightly	Moderately	Very	Extremely

5. Last night, did you sleep with the windows...
   ☐ Closed
   ☐ Partially open
   ☐ Completely open

6. Last night, did somebody share the bed with you (e.g. partner, child, pet)?
   ☐ Yes
   ☐ No

HEART RATE DEVICE

Software Development

Data Splitter

Automatic Arousal Detection
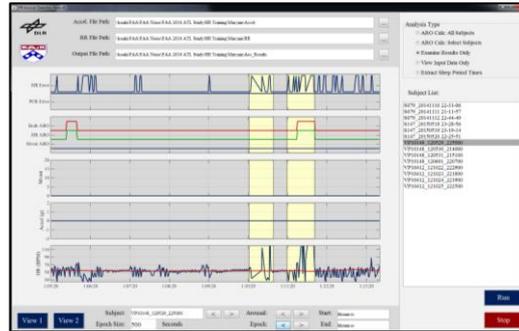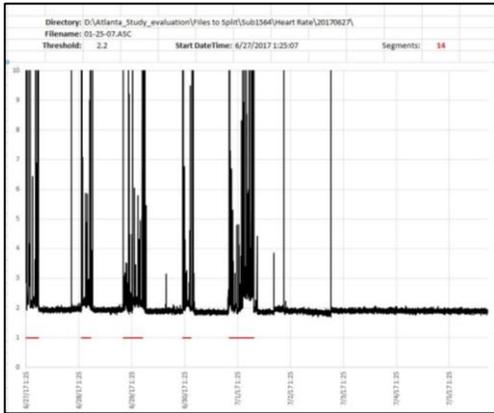
MP3 Conversion to Sound Pressure Levels
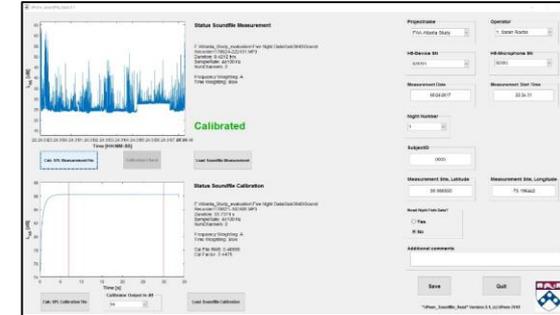
Respiratory Movement Visualization
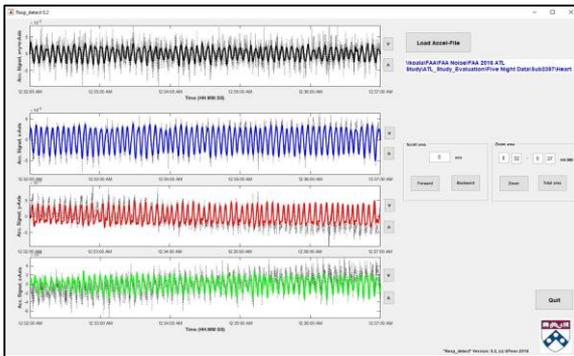
Noise Event Classification

Time Drift Correction

y = -0.0160959482x - 1.8561217005

13
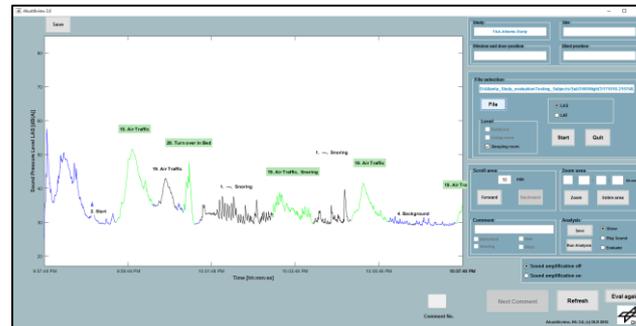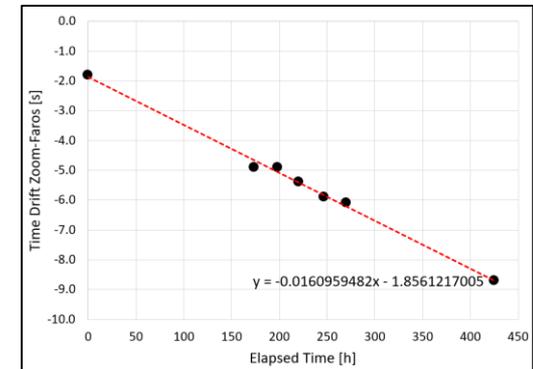
Study Status 3/21/2022
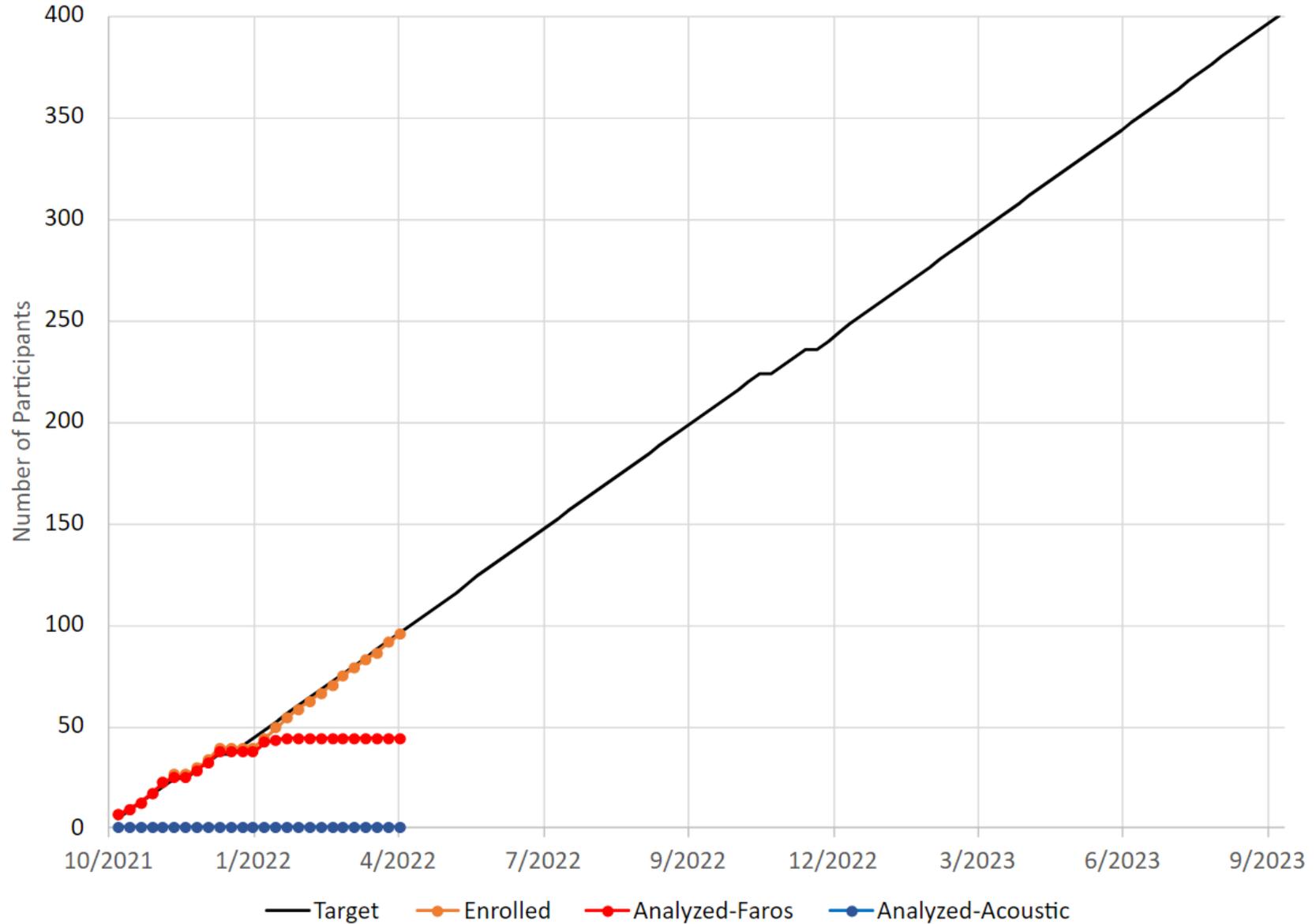
Next Steps

- Finalize data acquisition in October 2023

- Analyze data and generate report by October 2024

Acknowledgements