



Title: Assessing the health effects of six months of simulated wind farm

infrasound: A community-based randomised controlled trial

Short title: Community-based study of health effects of infrasound

Co-Principal Investigators:

Prof Guy Marks (Respiratory Physician and Epidemiologist, Woolcock Institute and University of New South Wales)

Dr Brett Toelle (Research Leader, Respiratory and Environmental Epidemiology, Woolcock Institute and University of Sydney)

Dr Christine Cowie (Environmental Epidemiologist, Woolcock Institute and University of New South Wales)

Chief Investigators:

Prof Ron Grunstein (Sleep Physician & Research Leader, Woolcock Institute and University of Sydney)

Dr Renzo Tonin (Acoustic Engineer, Renzo Tonin Associates)

A/Prof Nathaniel Marshall (Epidemiologist at the Woolcock Institute and University of Sydney)

A/Prof Miriam Welgampola (Neurologist, University of Sydney)

Prof Nick Glozier (Psychiatrist, University of Sydney)

Dr Craig Phillips (Clinical Physiologist, Woolcock Institute and University of Sydney)

A/Prof Delwyn Bartlett (Psychologist, Woolcock Institute and University of Sydney)

Associate Investigators:

Mr Gunnar Unger (Engineer, Woolcock Institute)

Dr Bruce Walker (Acoustic Engineer, Walker Consulting, California) **Dr Angela D'Rozario** (Postdoctoral Research Fellow, University of Sydney)

Mr Garry Cho (Study Coordinator, Wind Farm Lab Study, Woolcock Institute)

Ms Wafaa Ezz (Study Coordinator, Wind Farm Home Study, Woolcock

Institute)

Lead Study Coordinator: Ms Wafaa Ezz (Environmental Epidemiologist, Woolcock Institute)

Acoustic Engineer: Mr Sankalp Shukla (Graduate Engineer, Woolcock Institute)

Protocol No: X17-0235 & HREC/17/RPAH/351

Trial Registration: This study will be registered with the Australasian and New Zealand

Clinical Trials Registry (ANZCTR) - www.anzctr.org.au

Protocol Version: V 1.0, 28-JUN-2017

Funding source: This study is funded by National Health and Medical Research Council of Australia (NHMRC) through the Targeted Call for Research into Wind Farms and Human Health Application No. 1113615

This study will be performed in the homes of participants living in regions outside of the Sydney metropolitan area.

We would like to acknowledge the contributions of Nurul Yakob and Joshua Aung-Hlaing Way, Master of Public Health (MPH), University of Sydney students. Nurul and Joshua developed components of the protocol while completing credit points in PUBH5034 Public Health Capstone.

Contact person: Dr Brett Toelle

Woolcock Institute for Medical Research Email: brett.toelle@sydney.edu.au

Ph: 9114 0462

Ms Wafaa Ezz

Woolcock Institute for Medical Research

Email: Wafaa.ezz@sydney.edu.au

Ph: 9114 0493

Contents

| 1. lı | ntroduction6 |
|----------|---|
| 2. S | tudy Objectives9 |
| 3. E | xperimental design9 |
| 4. N | Methods: Participants, interventions, and outcomes 10 |
| 5. E | ligibility criteria10 |
| 6. S | tudy Interventions11 |
| 7. C | Outcomes |
| Tab | le 1. Screening and Outcomes Measurements14 |
| 8. P | Participant timeline17 |
| 9. S | ample size19 |
| 10. | Recruitment19 |
| 11. | Methods: Assignment of interventions |
| 12. | Methods: Description of study procedures21 |
| 13. | Data Management30 |
| 14. | Statistical Methods30 |
| 15. | Methods: Monitoring |
| 16. | Adverse Events Reporting31 |
| 17. | Auditing31 |
| 18. | Ethics and dissemination |
| 19. | Protocol amendments |
| 20. | Confidentiality32 |
| 21. | Declaration of Interests |
| 22. | Access to data |
| 23. | Ancillary and post-trial care32 |
| 24. | Dissemination policy |
| A. | Online Registration and Consent forms |
| В | Questionnaires |
| | Online Screening- Ethnicity, Lifestyle, Medical History, Medication, Sleep disorders patterns and Attitudes on Wind farms |
| | Actiwatch and Sleep Diary53 |
| Б. Е. | Neurootology55 |
| F. | Polysomnography (PSG) setup |
| | Neurocognitive Test |
| ~. | |

| н. | Cardiovascular and stress measures | 62 |
|-----|------------------------------------|----|
| Ref | ferences | 63 |

1. Introduction

Background and rationale

The drive to develop renewable energies to reduce fossil fuel consumption has resulted in increasing efforts to harvest wind power as a method of renewable energy delivery. This has resulted in the construction of multiple wind turbine clusters or "wind farms" in rural areas in Australia to generate power.

Health concerns

Implementation of wind power programs has been opposed by a number of communities, in part due to claims that wind farms pose a risk to health. Concerns have largely focused on audible or non-audible noise, such as infrasound, alleged to cause a range of negative effects on sleep, vestibular function and mood. Some people have referred to this constellation of symptoms as wind turbine syndrome (WTS).

Wind Turbine Syndrome (WTS)

WTS refers to a cluster of symptoms reported in case studies by Pierpont.(1) In that series individuals reported sleep disturbance, headache, tinnitus (ringing in the ears), a sensation of pressure in the ears, dizziness, vertigo, nausea, visual blurring, palpitations, irritability, problems with concentration and memory and panic episodes associated with sensations of internal pulsation or quivering when awake or asleep.(1) In that report, the symptoms typically improved during holidays or other withdrawal from the wind turbine environment and returned with re-exposure. There are case reports of WTS being present in one family member but not in another who lives in the same dwelling.(2) It has been proposed that people who are particularly 'sensitive' to noise may be at greatest risk. It has been argued that WTS is caused by infrasound generated by wind turbines.(1, 3, 4)

Alternative Explanations

Some experts have discounted the association between the symptoms of WTS and exposure to noise from wind turbines. They suggest the symptoms are the result of a nocebo effect, in which a patient can be convinced that something benign is making them sick. It is argued that the annoyance and health effects some people experience when unwanted turbines are erected in their local areas are more strongly related to subjective factors such as the visual impact of the turbines, attitudes towards wind energy and whether there is economic benefit from turbines, rather than to noise itself, both audible and inaudible (i.e. infrasound).(4, 5) This level of annoyance may be the primary mediating agent causing sleep disturbance and increased psychological distress.(6) Stress is considered another mechanism by which noise can impact on human health.(7) Where stress effects are present, they may be dependent on the level of annoyance induced by the noise.(8)

Noise from wind turbines

Wind turbine noise comprises the following range of spectra of relevance to this study:

- i. Infrasound (frequencies less than 20 Hz),
- ii. Low Frequency (LF) sound (frequencies 20-200 Hz)
- iii. High Frequency (HF) sound (frequencies above 200 Hz).

Whilst infrasound is regarded as being below the audible range, if its level is high enough it can be "sensed". This sensation is best described as a sensation of pressure on the ears(9) or a sensation or sound of deep humming/rumbling.(2) There is no sense of pitch attributable to infrasound. In contrast, noise in both the LF and HF range is usually audible with a sense of pitch.

Wind turbine noise encompasses the whole of the sub-audible and audible frequency spectrum – infrasound, LF sound and HF sound including amplitude modulation ("swish") effects of the higher frequency sounds. It is not known which of those components contribute to annoyance and which contribute to the alleged health effects.

Infrasound

The nature of infrasound is now well understood(10) based on acoustical studies performed at Bluff Wind Farm (SA), Cape Bridgewater Wind Farm (VIC) and Shirley Wind Farm (USA).(11) The sound is comprised of the blade pass frequency (typically 0.7-0.8Hz) and its harmonics. The maximum sound pressure level at these frequencies was 89.5dB Lin Peak (recorded at Shirley Wind farm).

Community concerns are focused on infrasound

The main community group advocating that wind farms have deleterious effects on health is the Waubra Foundation. The foundation's chair, Mr Peter Mitchell recently served as an observer on the NHMRC Wind Farms Health Effects Reference Group. The foundation recently published a statement "Acoustic Engineering Investigation into Airborne and Ground-Borne Pressure Pulses from Wind Turbines at Cape Bridgewater" (12) (Mr Peter Mitchell, personal communication to Prof Grunstein) which summarises their concerns. It states that although infrasound is only audible at very high levels, "it can be damaging to the human body at levels well below audibility". Moreover the document states that "Infrasound has long been known to be dangerous and harmful to humans, especially with chronic exposure. Infrasound persists for much greater distances than audible sound and, unlike audible sound, penetrates virtually all building structures (including double glazing) with ease; and often increases the impact by resonating with internal structures in the house". While infrasound is ubiquitous, anti-wind farm community groups state that wind turbines have a specific infrasound signature or profile that differs from common sources of infrasound such as ordinary wind, household appliances or waves on a beach. This profile is "a necessary tool for investigating noise from wind turbines anywhere".

In addition, the foundation recommended that research also measure subjective "sensation" of vibration related to infrasound by use of specific self-report scales, investigation be undertaken inside houses and continue over sufficient periods of time, such

as 6 weeks. It is the infrasound component of the noise that is claimed by those suffering nausea, dizziness and other symptoms that is the primary cause of their symptoms.

Given these views from community groups and the lack of high quality research on health effects identified by the NHMRC Reference Group,(13) we propose that the correct approach to addressing the issue of wind farm noise and health effects is to focus on robustly assessing the effects of infrasound using a synthesised sound that matches the infrasound profile of wind farms in a randomised controlled trial of exposure.

Possible biological mechanism for vestibular effects

The following observations indicate that infrasound may be capable of producing audio vestibular disturbances, particularly in susceptible individuals.

- 1) At very low frequencies, the cochlear outer hair cells (innervated by type II afferents which do not participate in conscious hearing) are stimulated by sounds below the audible range.(14)
- 2) Structures involved in endolymph volume regulation are influenced by infrasound. In experimental animals, brief (1-2 min) exposures in the moderate to intense ranges of low frequency tones have induced endolymphatic hydrops.(15)
- 3) Humans, monkeys and guinea-pigs do not show evidence of vestibular activation by high levels of infrasound(16) but some inner ear pathologies lower the thresholds for vestibular activation due to the presence of an additional low resistance pathway or "third window": superior semicircular canal dehiscence, large vestibular aqueduct syndrome.(17, 18) Further, endolymphatic hydrops and vestibular migraine, which are characterized by sound hypersensitivity, may also provide additional biologically plausible pathways by which infrasound may have health effects. Hence, there is a biologically plausible mechanism for the physiological effects of infrasound. However, as yet there is no evidence that these effects actually occur. The study proposed here is designed to provide data in this area.

Noise sensitivity and annoyance

Noise sensitivity and annoyance are considered to be related but not identical concepts.(19) Noise sensitivity is a distinct psychological trait and refers to the predisposition to perceive noisy events. Annoyance is an attitudinal dimension indicating the extent to which noises are evaluated unfavourably.(20) About 20-30% of individuals self-describe as noise sensitive. Although noise sensitivity does not differ by sex, it tends to increase with age.(21) Noise-sensitive individuals have noise "annoyance thresholds" approximately 10 dB lower than noise tolerant individuals(22) and usually react to environmental sound more easily, evaluate it more negatively, and experience stronger emotional reactions compared to noise tolerant people.(23) People who are noise sensitive are more likely than others to report annoyance due to exposure to sound at low and moderate intensity.(24) Noise sensitivity and annoyance are usually measured by self-report questionnaires. In this study, we will selectively recruit subjects who report increased noise sensitivity and measure annoyance from study exposures in each study arm.

2. Study Objectives

To investigate whether six month infrasound exposure, compared with the sham exposure, is associated with impaired sleep quality (the primary outcome, measured as wake after sleep onset, WASO), an excess of symptoms that have been attributed to Wind Turbine Syndrome, annoyance, sleepiness, impaired neurobehavioural and neurocognitive performance, impaired vestibular function, increased arterial stiffness and increased blood pressure (secondary outcomes).

Secondly, to investigate whether experiencing an excess of symptoms that have been attributed to WTS is related to baseline levels of stress and anxiety.

A complementary short-term laboratory-based study is underway to measure the short term health effects of exposure to infrasound, sham (negative control) and traffic noise (positive control). http://www.ANZCTR.org.au/ACTRN12617000001392.aspx

3. Experimental design

This community based randomised controlled trial has two parallel groups and will be conducted within the homes of non-metropolitan participants:

- 1) simulated wind turbine sound (infrasound, test exposure)
- 2) absence of sound (sham, control exposure).

Participants will be randomised to either the infrasound or sham exposure. Four speakers that are visually identical but that deliver either infrasound or sham will be installed in the bedrooms of participants. Participants and research staff conducting clinical assessments will be blinded to the test and control exposure (as the infrasound is inaudible). The members of the team who will be unblinded are the acoustic engineers who install the speakers in the home, conduct checks and maintenance and the chief investigators responsible for the randomisation schedule.

The speakers will be in place for six months and clinical outcome assessments will be conducted at the three month and six month time points.

4. Methods: Participants, interventions, and outcomes

Study setting

Non-metropolitan sites anywhere within NSW, will be selected based on a process that takes into consideration:

- 1) Location the site is in a region conveniently located to minimise travel time from Sydney for the researchers.
- 2) Topography the landscape of the site will be similar to the type of environment where wind farms are usually constructed.

An example of a region of interest is The Southern Highlands, south-west of Sydney, because it satisfies the two requirements listed above.

Firstly, it is only 110 kilometres from Sydney, allowing for a relatively short travel time.

Secondly, the Southern Highlands have the potential for high winds because the region lies along the elevated section of the Great Dividing Range. Therefore, certain locations in this region have the optimal combination of average wind speeds that are high and consistent, as well as flat landscapes, making it an ideal location for a wind farm. There are currently no wind farms present in the region; the closest is the Taralga Wind Farm that is approximately 50 kilometres from Bowral.

We are also interested in recruiting in the Camden/Macarthur region as areas closer to Sydney as well as the population density being somewhat similar to population densities around windfarms. This area is also more than 50 kilometres away from an already existing windfarm.

5. Eligibility criteria

5.1 Inclusion criteria

- 1. Aged 18 or above (If you consent to participate in this study you agree that persons under the age of 18 will not be permitted to sleep in the bedroom where the speakers are installed
- 2. Noise sensitive individuals -defined as Weinstein's Noise Sensitivity Scale (WNS) Score >58 (Appendix B)
- 3. Normal hearing
- 4. Regular sleep of 5.5 hours / 24 hours for 7 days as demonstrated by actigraphy
- 5. Fluent in English, to be able to answer computerised questionnaires and undergo neurocognitive assessments in English

5.2 Exclusion criteria

- 1. Rotating shift worker
- 2. Planning to be away from home for more than a month during the study period

- 3. Major psychiatric disorders
- 4. Use of any hypnotic medications or other medications that interfere with sleep within the last month
- 5. Breastfeeding, pregnant or attempting to become pregnant women in the household
- 6. Young children (under 5 years) living in the home

6. Study Interventions

Participants that meet the eligibility criteria will be randomised to either:

- 1) simulated wind turbine sound at 93dB Pk (infrasound, test exposure)
- 2) absence of sound (sham, control exposure).

Four 600mm x 600mm cube speakers (photo below) will be installed in the bedroom of each participant. For participant convenience, these speakers can be placed in variable configurations within the participant's bedroom. The speakers are wired together and are powered by a single cord that plugs into a domestic power point.

In addition to the speakers there will be two microphone stands with microphones placed in the bedroom. Neither microphone will collect sound content or conversation, but they will collect the sound level in decibels of 1) infrasound and 2) audible sound.

The speakers and microphones will operate continuously over the six month period of the study. By agreement with the participant, the acoustic engineer will schedule regular visits to the home to assess the correct functioning of the equipment. These visits may be up to weekly in the first month of operation and then monthly or as required for the remaining five months of operation. All participants will be reimbursed for expenses associated with the use of electricity to run the speakers. The acoustic engineer will be unblinded to group allocation and will be the contact point for participants who want to discuss anything regarding the speakers, microphones, electricity consumption or other exposure related query, thus ensuring the participant and clinical assessment staff remain blinded to group allocation.

6.1 Discontinuing

Withdrawal criteria

Participants will be informed that they have the right to withdraw from the study at any time, without prejudice to any medical care (such that might be required if we incidentally identify a medical condition), and are not obliged to state their reasons. Additionally the investigator may withdraw a participant at any time for the following reasons:

- If any of the study exclusion criteria are diagnosed
- Protocol violations
- Adverse events

Discontinuation of the study

The study may be discontinued at any time on the advice of the responsible principal investigators on the basis of new information regarding safety. A Data Safety Monitoring Board has been constituted to provide advice to the investigator team with regard to participant safety (Section 15.1). Additionally, the study may be terminated if progress is unsatisfactory.

In the case of premature termination or suspension of the experiment, the investigator will inform the study participants and ensure appropriate follow up in the unlikely event this is required clinically. In addition, the appropriate ethics committee will be informed.

Procedure to withdraw

Participants with clinically significant abnormalities requiring discontinuation will be followed until recovery from the abnormality. If the study is discontinued for safety reasons, the investigators will contact all affected participants within a week to inform them of the termination of their involvement in the study. Participants discontinuing from the study may be replaced. A new participant number must be issued for the new participant.

If a participant fails to respond to telephone contact or is consistently unavailable for home visit, attempts will be made to ensure that the reason for not communicating is not an adverse event (bearing in mind that the participant is not obliged to state his/her reasons).

7. Outcomes

Primary outcome measure:

Changes in wake after sleep onset (WASO) as determined by 4 EEG channel polysomnography with portable recorder at baseline, 3 and 6 months. We will compare the differences between infrasound and sham sound.

Secondary outcome measures:

EEG parameters from the overnight sleep studies - Sleep latency, sleep staging, sleep stage shifts, arousal frequency and power spectral analysis for sleep microarchitecture analysis.

Tertiary Outcome Measures:

Neurocognitive tests (Section 12.8):

N-back

Tower of London

<u>Cardiovascular and stress measures (Section 12.9):</u>

Office blood pressure Pulse wave velocity

Heart rate variability

Blood markers- highly sensitive CRP, interleukin (IL)-6, TNF-alpha and HbA1c

Hair Cortisol

Neurotological tests (Section 12.4):

Vestibular Evoked Myogenic Potentials (VEMP)

Video Hit Impulse Tests (vHIT)

Audiometry

Otoacoustic Emissions (OAE)

Videonystagmography (VNG)

Matted Romberg test

Unterberger test

Vestibular Event Monitoring

Screening, Phenotyping and Explanatory Questionnaires and measures (Appendix B & C):

Insomnia Severity Index (ISI) questionnaire

Weinstein's Noise Sensitivity Scale (WNS) score

Depression Anxiety and Stress Scale (DASS-21)

Kessler 10 (K10)

EYSENCK Personality Questionnaire-Revised

Noise Annoyance Scale

Symptom Visual Analogue Scales

Warwick Edinburgh Mental Well-being Scale

Ethnicity

Medical history

Medication

Sleep Disorders and Patterns

Epworth Sleepiness Scale

Health and Work Performance Questionnaire

Shift work questionnaire

Attitudes on Windfarms

Exit questionnaire

Table 1. Screening and Outcomes Measurements

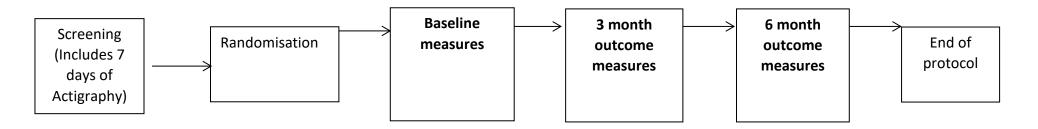
| Item | Staff | Screening | Baseline | 3month | 6month |
|---|-------|-----------|----------|--------|--------|
| Screening - online | | | | | |
| Weinstein's Noise Sensitivity Scale (WNS) | | Х | | | |
| Cardiovascular, sleep, or neurological chronic | | | Х | | |
| illness | | | | | |
| Clinically significant sleep disorders | | Х | | | |
| Major psychiatric disorder | | Х | | | |
| Hypnotic or anti-psychotic medication | | Х | | | |
| Shiftwork Questionnaire | | Х | | | |
| Breastfeeding, Pregnant or planning pregnancy | | Х | | | |
| Child under the age of 5 years | | Х | | | |
| Insomnia Severity Index | | Х | Х | Х | Х |
| Epworth Sleepiness Scale | | | Х | Х | Х |
| DASS-21 | | | Х | Х | Х |
| Kessler-10 | | | Х | Х | Х |
| Attitudes on Wind farms | | | Х | | |
| Exit Questionnaire | | | | | Х |
| Screening – home | | | | | |
| Actigraphy and Consensus sleep diary (7 nights) | | Х | | | |
| Audiometry | | Х | | | |
| Clinical Assessments - home | | | | | |
| Sleep and Wake Measurements | | | | | |
| Home 4 EEG channel polysomnography | | | Х | Х | Х |
| (1 night) | | | | | |
| Neurobehavioural and neurocognitive | | | Х | Х | Х |
| performance | | | | | |
| Actigraphy (7 nights prior to PSG) | | | Х | Х | Х |
| Sleep Disorders and Patterns Questionnaire | | | Х | Х | Х |
| Cardiovascular and Stress measurements | | | | | |
| Height, Weight, Waist circumference | | | Х | Х | Х |
| Office Blood Pressure | | | Χ | X | Χ |
| hsCRP | | | X | Χ | Χ |
| IL-6 | | | Χ | X | Χ |
| TNF-alpha | | | X | X | Χ |
| Hair cortisol | | | Χ | X | Χ |
| HbA1c | | | X | X | Х |
| Pulse wave velocity | | | Χ | X | Χ |
| Annoyance and Wind Turbine Syndrome | | | | | |
| measurements | | | | | |
| Visual Analogue Scale questionnaire | | | Х | Х | Х |
| Noise Annoyance Scale | | | Х | Х | X |
| Psychological measurements | | | | | |
| EYSENCK Personality Questionnaire-Rev. | | | Х | | |
| Warwick Edinburgh Mental Well-being Scale | | | Х | Х | Χ |

| (WEMWBS) | | | |
|----------|--|--|--|
| | | | |

| Item | Staff | Screening | Baseline | 3month | 6month |
|---|-------|-----------|----------|--------|--------|
| Clinical Assessments - home | | | | | |
| Neuro-otological measurements | | | | | |
| Audiometry (inc. tympanometry,otoscopy) | | | Χ | Χ | Х |
| Vestibular Evoked Myogenic Potentials | | | Χ | Χ | Х |
| (VEMP) | | | | | |
| Video Hit Impulse Tests (vHIT) | | | Χ | Х | Х |
| Audiometry | | | Χ | Χ | Χ |
| Otoacoustic Emissions (OAE) | | | Χ | Χ | Χ |
| Videonystagmography (VNG) | | | Χ | Χ | Х |
| Matted Romberg test | | | Χ | Χ | Χ |
| Unterberger test | | | Χ | Χ | Х |
| Vestibular Event Monitoring | | | Х | Х | Х |
| | | | | | |

8. Participant timeline

Figure 1: Timeline for study protocol



From Baseline to 6 month outcome the acoustic engineer will make weekly in the first month, then monthly for the next five months visits to the home to check on the speakers, download data from the recording devices and address participant concerns

8.1 Enrolment/screening

Screening of suitable participants will be undertaken in two phases. The first phase will be conducted via an online screening questionnaire. The second phase will combine a non-invasive technique (wrist actigraphy and sleep diary) for the at-home measurement of normal sleep/wake cycles and an at home clinical assessment with the study research team.

Phase 1: Online Screening

Online screening procedure is described in 12.3

All participants who attempt stage 1 of screening (i.e. receive a unique login, see 13.2.2) will be assigned with a sequential screening number (i.e. S1, S2 etc)

Phase 2: Home Screening

The home screening procedure is described in 12.3.1

If a potential participant is deemed suitable by the online screening procedure they will be contacted by the study coordinator and a face-to-face screening appointment at their home will be arranged. For 7 days preceding this appointment they will wear an Actiwatch 2 and asked to fill out a sleep diary. Participants will be sent instructions with the device and diary via courier. Actigraphy will be visually checked to ascertain whether the participant has a normal 24 sleep/wake cycle and biologically sufficient sleep (at least an average of 5.5 hours per 24 hours). Sleep diaries will also be kept to correlate with actigraphy data.

At the face-to-face screening at home, participants will have audiometry and those with impaired hearing will be excluded.

If a participant is willing and eligible they will then have the study fully explained to them and will be given the opportunity to ask questions before they give written informed consent to enrol in the study at this visit. They may also make that decision later and return informed consent documents via email, post or in person

8.2 Baseline, 3 months and 6 month home visits

Eligible participants who have given informed consent will have a baseline visit scheduled during which time they will complete a range of clinical assessments as described in Table 1.

Outcome measures will be collected at 3 and 6 month home visits. These visits will be conducted at a convenient time for the participant. Prior to the 3 and 6 month outcome assessment the participant will be sent an Actiwatch 2 to wear for two weeks prior to the visit. They will also have an overnight polysomnography (sleep study) performed. The research assistant will visit the home in the evening to connect the leads for the study. They will also provide instructions to the participants. The research assistant will return early the next day to collect the equipment.

8.3 Infrasound or Sham speaker installation and monitoring

The acoustic engineer will schedule a visit to the home soon after baseline testing has been completed. At this visit, either infrasound or sham speakers will be installed into the bedroom of the participant. In addition to the 4 x 600mm cube speakers we will place a monitoring box and 2 microphones in the bedroom.

The acoustic engineer is unblinded and will advise participants that if they have any concerns about the speakers that they should contact him directly and not discuss this with other members of the team who do not know what type of speaker is installed in the bedroom. Additionally, the participants will be informed that their electricty bill may increase and that they will be reimbursed for this expense. Again, this is to be discussed with the unblinded acoustic engineer who installed the speakers and not any other member of the team.

The acoustic engineer will arrange regular visits to the home of participants to check that they speakers are performing as designed and that the monitoring equipment is collecting infrasound or sham sound exposure information. These visits will be weekly in the first month, then monthly for the next five months or as required. He will download data and bring this back to Woolcock Institute for secure storage.

8.4 Reimbursement

Participants will be fully reimbursed for the additional cost of electricity for running the speakers and microphones. We anticipate that this amount will be in the range of \$60 to \$120. We will offer a payment of \$1,000 to cover electricity and the inconvenience of having the speakers in the home and participating in the testing for all participants involved in this study.

9. Sample size

From previous studies, the between-subject standard deviation in wake after sleep onset (WASO) is conservatively estimated at 20 minutes. Most trials of treatments for insomnia, for instance, regard a change of 15 minutes or more in WASO as being clinically meaningful. A sample size of 120 participants (which includes allowance for 22 dropouts) will have 85% power to detect a 0.25 effect size (Cohen's f).

10. Recruitment

Number and source of participants

The target number of participants is 120. This will provide 60 participants in the infrasound group and 60 participants in the sham group.

Participants will be found by public advertising in local newspapers, community radio, television media and social media through the Woolcock website and its database of

| research volunteers which will direct all volunteers to the online screening website (Appendix A). |
|--|
| |
| |
| |
| |
| |
| |
| |
| |
| |

11. Methods: Assignment of interventions

11.1 Randomisation

Participants will be randomised to either infrasound or sham through the use of a preprogrammed randomization plan from http://www.randomization.com. All study personnel who collect clinical outcomes from participants will be blinded to group allocation. The only unblinded personnel will be the acoustic engineer and two senior chief investigators who independently check that the randomisation schedule is being implemented as designed.

11.2. Blinding

Expectations on the part of participants and investigators may influence the effect of the exposure (infrasound) and, more particularly, may influence the measurement of those effects, especially the subjective (self-reported) outcomes. To avoid the potential for this measurement bias, it is important that both participants and the investigators who are measuring outcomes are blinded to the intervention group. Fortunately, as infrasound is, by definition, inaudible, this is readily achieved by the use of a sham device that appears the same as the infrasound device, but which does not produce any sound. Only the unblinded acoustic engineer will have knowledge of the exposure and they will never disclose this group allocation to the participants or staff/investigators who interact with participants.

12. Methods: Description of study procedures

12.1 Informed consent

Each potentially eligible participant will be informed of the study's objectives and overall requirements by the lead study coordinator or one of the principal investigators using the participant information sheet and informed consent form, and they will be provided with a copy of the forms. If the participant is willing to participate in the study, they will be requested to give written, witnessed, informed consent.

12.2 Simulated infrasound waveform and sham infrasound

The infrasound attributable to wind turbines will be simulated using a 0.8 Hz trapezoidal-shaped waveform with 16 harmonics (Figure 2). Conventional audio systems are not capable of generating sound levels at 0.8 Hz. Therefore, a purpose built apparatus will be utilised (Figure 2).

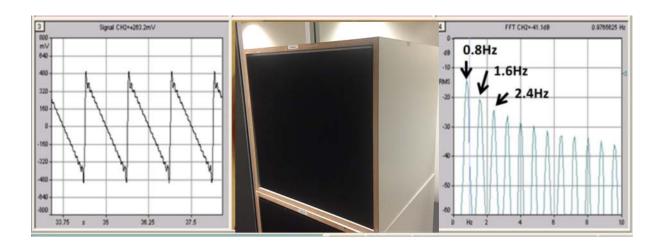


Figure 2. The Walker Speaker Boxes and the Simulated Spectrum

The apparatus generates the required waveform using three 18" sub-woofer drivers in a timber enclosure. Four 18" JBL high power sub-woofers will be used, each constructed separately in timber boxes with integral power amplifiers. The separating gap between the enclosures is open on all four sides of each infrasound cube (i-cube) from which the infrasound pressure waveform will be emitted. The 4x 600mm i-cubes will be placed in convenient corner locations within master bedroom. The i-cubes will be electronically connected by cable to enable the infrasound waveform signature to be fed to all four speakers simultaneously. Sham units will be constructed to appear identical to the active (infrasound-emitting) i-cubes, but will not emit any audible sound or infrasound.

12.2.1 Monitoring infrasound exposure

Sound level in the master bedroom will be measured by a low frequency microphone (Fig 3)type G.R.A.S. 40AZ which is a ½" Pre-polarised Free-Field Microphone connected to a G.R.A.S. Type 26CG ½" Low Frequency CCP Preamplifier. The G.R.A.S. 40AZ microphone has a frequency response of 0.5Hz to 20 kHz (+/- 2dB) which encompasses the range of the study. As well, a G.R.A.S. 12AL 1-Channel CCP Power Module, custom built 50Hz low pass filter/amplifier and Graphtec GL220 data logger with USB hard drive will be utilised for data acquisition. The infrasound will be recorded on the USB hard drive for post processing. Peak sound levels will be measured for each 15 minute interval. All equipment will be certified as conforming to appropriate international standards at the NATacoustic NATA registered laboratory in Sydney. Only the unblinded acoustic engineer will have access to this data.



Figure 3. Microphone stand with infrasound and audible sound microphones

12.3 Online screening website

Through various recruitment strategies participants will be referred to an online website to register their interest (Appendix A) where they will be asked to register with their details (Name, Phone number, Email address and Postcode) and in return, participants will be sent a unique login and instructions to complete an online questionnaire for this study that will be used as a tool to help screen and phenotype participants. The online questionnaire is a series of questionnaires (Appendix B & C) asking about general health, medication use and medical history, lifestyle and sleeping patterns. Furthermore, participants will answer various questionnaires regarding their psychological wellbeing which will further assist in the decision determining the suitability for each participant. Some questionnaires will be automatically scored using standardised scoring algorithms that will help in excluding

participants who are unsuitable and flagging participants who require a decision to be made by members of the research team. Participants will be asked to give consent before beginning the questionnaire for screening online and, if eligible, at a home visit.

12.3.1 Home screening

If shown eligible on the online screening, participants will be contacted by a member of the research team to organise a face to face appointment at home. Prior to the home visit participants will be sent an Actiwatch 2, a painless watch-like device worn around the wrist to monitor sleep and wake cycles and activity patterns (body movement and ambient light). Accompanying the Actiwatch 2, participants will be sent and asked to fill out a sleep diary self-assessing their sleep whilst at home. Participants will be asked to wear the Actiwatch 2 and complete the sleep diary for at least 7 days before coming in to their face-face appointment.

At the face to face home screening the participant will have their hearing tested. Participants will go through various hearing tests (Section 12.4.3)

12.4 Neurotological assessment (Appendix E)

Neurotological testing will occur during the baseline, three and six month visits. Neurotological tests will be performed in a quiet room and therefore will not be occur during any experimental noise conditions.

12.4.1 Examination

Participants will firstly be asked some questions regarding their clinical history that may affect the neurotological examination (e.g. Do you experience vertigo?). This will be followed by two tests. The matted Romberg test assesses a participant's ability to hold their balance whilst standing on a mat with their eyes closed. The second test, the Unterberger will require participants to walk on the spot with their eyes closed. This test will measure the angle of rotation from the line marked.

Clinical ear examinations (Otoscopy and Tympanometry) will also be performed prior to any tests to ensure that there is not any obstruction in the ear canals and determining eardrum function.

- i) Otoscopy: Examines if there are any structural changes in the tympanic membrane and ear canal using a device called a otoscope.
- **ii) Tympanometry:** A probe like device will be inserted into the ear canals and play a tone to measure the movement in the eardrum in response to changes in pressure caused by the tone.

12.4.2 Videonystagmography (VNG)

Participants will be asked to wear a goggle-like device that is equipped with a camera to track the pupils of the eye. Participants will be instructed to keep their eyes wide open and gaze ahead or on a specific target. Following this, participants will then be asked to lie in a supine position where they will be rolled to each side by the examiner whilst tracking the eye movements.

12.4.3 Audiometry

Formal testing of air and bone conduction hearing thresholds will be undertaken using a laptop-based audiometer. This test is designed to measure hearing acuity by a variation of tones in pitch and sound intensities played through a set of headphones. This test will be performed in a quiet room.

12.4.4 Otoacoustic Emissions test

Measures the otoacoustic emissions (OAEs) produced by the outer hair cells of cochlea as part of the pre-neural active process within the cochlea. Otoacoustic emissions can occur spontaneously or they can be elicited by presenting sound into the ear canal. The test is performed by inserting a foam earbud tip into the ear and a distortion product tone or broadband click will be played to elicit this response. Otoscopy and tympanometry will be performed before to test middle ear integrity as middle ear dysfunction is contraindicated in this test as it will not produce a response.

12.4.5 Video head impulse test (VHIT)

Measures the vestibular function through testing the vestibulo-ocular reflex. The participants will wear lightweight goggles which will track eye and head movement concurrently using a high speed camera and a motion sensor in the goggles whilst the participant is viewing a target at eye level 1.5 metres away. The examiner firmly holds the participant's head and delivers brief, unpredictable, low amplitude (10-20 degrees) and high velocity (150-300 degrees/s) head movements in the plane of the 3 pairs of semicircular canals. Head and eye velocity are measured and displayed in real time. For each semicircular canal tested, in the presence of an intact vestibulo-ocular reflex (VOR), each head impulse generates an equal and opposite eye movement and the "gain" of the angular VOR in this canal plane (eye velocity/head velocity) is close to 1. Three dimensional video head impulse testing includes assessment of the angular VOR in all 6 semicircular canal planes. The VHIT quantifies dysfunction of semicircular canals.

12.4.6 Vestibular Evoked Myogenic Potential (VEMP)

Measures vestibular function through activating the otolith organs in the ear to elicit "vestibular evoked myogenic potentials". Cervical and ocular vestibular evoked myogenic potentials (cVEMP and oVEMP respectively) are two tests which will be performed together. The participant will have EMG electrodes placed on the face and the neck whilst in a supine position.

- i) Cervical Vestibular evoked myogenic potential (cVEMP): Measures the functionality of the saccule by activating a myogenic potential through playing sound through headphones. To ensure proper contraction of the muscle participants will be instructed to lift their head and turn to each side. This produces a muscle reaction in the sternocleidomastoid muscle which is recorded through the EMG electrodes.
- **ii)** Ocular Vestibular evoked myogenic potentials (oVEMP): Measures the functionality of the utricle which is activated through tone bursts/vibrations against the participant's forehead using a 'mini shaker' oscillator (like gentle tapping on centre of forehead). The

participant will be asked to look up as far as possible with their eyes as the oscillator is vibrating against the forehead.

12.5 Psychological and psychiatric health

The following questionnaires will be measured baseline and at three months and six months (see Appendix B)

Baseline and 3 month and 6 month outcomes:

- 1. Noise Annoyance Scale
- 2. Symptom Visual Analogue Scales
- 3. Warwick Edinburgh Mental Well-being Scale (WEMWBS)
- 4. Depression Anxiety and Stress Scale (DASS-21)
- 5. Insomnia Severity Index (ISI)
- 6. EYSENCK Questionnaire

Attitudes on Wind farms8. Kessler (10)

9. Depression Anxiety Stress Scale (DASS-21)

12.6 General health assessment

Anthropometric measurements such as height, weight, waist circumference and the blood pressures of each arm will be taken at the face to face home screening visit and the baseline, 3 month and six month outcome assessment visits.

12.7 Polysomnography (PSG) (Appendix F)

Home-based polysomnography (PSG) for assessment of sleep and sleep quality will include multichannel recording including oximetry, ECG, EEG, EMG, flow and chest and abdomen movement using a small portable recorder (Alice PDx, Philips Respironics). A sleep scientist will attach equipment in the late afternoon and retrieve it in the morning. Polysomnography data will be analysed by a single core laboratory at the Woolcock Institute of Medical Research (The University of Sydney, NSW, Australia) using standardised analysis and reporting protocols.

12.8 Neurocognitive Assessments

The computerised neurocognitive test battery will include the N-back and the Tower of London test. Neurocognitive tests will occur at baseline, three and six month clinical assessments.

12.8.1 N-back (2-back) (5 mins)

This test involves the participant monitoring a series of stimuli and requires them to respond whenever a stimulus is presented that is the same location as the one presented n trials previously, where n is a pre-specified integer, usually 1, 2, or 3. The task requires online monitoring, updating, and manipulation of remembered information and is therefore assumed to place great demand on a number of key processes within working memory.

12.8.2 Tower of London (3-5min)

This computerised test involves the presentation of two different arrangements of coloured balls on the monitor. The subject's task is to rearrange the first array of balls so that it matches the second array of balls using the minimum number of moves possible with the mouse. The positioning of the balls is constrained to the location of three pegs in each display. This test demands that the sequence of moves is carefully planned in advance before attempting the first move. Failure to engage in advanced planning of the sequence will result in initial moves blocking subsequent ball moves. This test involves using "executive" function, specifically forward planning, to solve a problem. Accuracy, determined as the number of moves, and speed, using time, variables can be obtained.

12.9 Cardiovascular and stress measures (Appendix H)

12.9.1 Pulse wave Velocity (10-15 minutes)

Pulse Wave velocity is the gold standard for measuring for aortic stiffness. The measurement is a painless, non-invasive test and entails inflating a cuff around a fully clothed thigh whilst simultaneously placing a pressure probe on the carotid artery of the neck across the skin. The test will require the participant to maintain a resting period of 10 minutes and 5 minutes measuring periods. This measurement will be recorded whilst in the exposure of the experimental noise conditions.

12.9.2 Heart rate variability

This will be measured through ECG leads which are attached during routine overnight sleep study. This will be analysed using PRANA® Software Suite.

12.9.3 Blood test for inflammatory markers

A blood sample will be taken on the last morning of each lab stay using standard venepuncture technique to measure inflammatory markers including: highly sensitive CRP, interleukin (IL)-6, TNF-alpha and HbA1c. Over the 3 clinical assessments a total blood volume of 130mL will be taken from each participant which is less than one routine blood donation (~400mL). Approximately, 40mL of blood will be taken from the arm at each visit. Three 8.5mL gold serum separating tubes and one 4mL purple EDTA will be sent to a local pathology laboratory and an extra two 8.5mL gold serum separating tubes will be centrifuged and the serum will be extracted and stored at -80°C at the Woolcock Institute.

12.10 Insomnia Severity Index (ISI) questionnaire (see Appendix B)

The ISI is a 7-item patient reported outcome measure that probes the severity of both the night time and daytime impact of insomnia and takes approximately 3 minutes to complete. Each item uses a 5-point Likert scale to capture a rating (0 = no problem; 4 = very severe problem) which add up to: no insomnia (0-7); sub-threshold insomnia (8-14); moderate insomnia (15-21); and severe insomnia (22-28). It will be completed at baseline, three and six month clinical assessments.

13. Data Management

All data will be collected in the home in written and computerised formats. Paper records shall be securely stored in locked cabinets at the Woolcock Institute of Medical Research for up to 15 years following the end of the study. Computerised data will be stored and backed-up on a secure cloud based, individual password protected database system (Research ToolsTM) which logs all access or changes to data back to individual users who will be given only access or change privileges to data which they require for their role. During data collection, only investigators named at the front of this protocol, the unblinded study statistician and the data safety monitoring committee will be allowed access to the study data under the supervision of the Principal Investigators. After study completion, a non-identifiable dataset (does not include information that could help identify a participant such as date of birth, address or ethnicity) may be published in an open access data repository. All data will be re-identifiable as, once randomised into the study, participants will be allocated an individual study code number. The master coding sheet will be kept in a password encrypted file and only investigators and research staff will have access to it. However, if needed, each individual will be able to be re-identified.

14. Statistical Methods

Generalised linear mixed models will be utilised for statistical analysis. WASO will be the dependent variable in the primary analysis. All other outcomes will be tested separately as dependent variables. Exposure (infrasound vs sham) will be the main fixed effect. As multiple outcome measures will be made (at baseline and at 3 & 6 month follow-ups) a "time" fixed effect will also be included and exposure-by-time interactions will be tested. The differences specifically at the 6 month time period will be the primary endpoint. In subanalyses we will also test whether changes in outcomes are influenced by whether people thought windfarms have health effects (expectancy) to establish whether this attribute modifies the propensity to experience WTS symptoms with exposure

15. Methods: Monitoring

15.1 Data monitoring

Because infrasound like this has not been used in experiments of longer than 2 hours duration a Data Safety Monitoring Board has been convened. The DSMB will oversee participant safety in both the laboratory study (Protocol No X16-0073 & HREC/16/RPAH/91) and this community based study by reviewing unblinded accumulated safety data pertaining to infrasound.

16. Adverse Events Reporting

Collection of adverse events will occur throughout the study.

Serious adverse events (SAE) are defined as any untoward medical occurrence that:

- Results in death
- Is an immediately life-threatening condition
- Requires hospitalisation or prolongs hospitalisation
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Results in any other important medical condition.
 The Ethics Committee will be notified of any SAE within 72 hours.

17. Auditing

The study will not be externally audited

18. Ethics and dissemination

18.1 Study conduct/ethics approval

The study will be conducted under the ethical jurisdiction of the Sydney Local Health District (SLHD) Ethics Committee at Royal Prince Alfred Hospital and will be performed in accordance with the Declaration of Helsinki,²⁷ the Australian Good Clinical Research Practice Guidelines²⁸ (Commonwealth of Australia, 1991) and the guidelines of the National Health and Medical Research Council for human research.²⁹

19. Protocol amendments

Any amendments to the protocol will be made in writing to the SLHD Ethics Committee after discussion with all co-investigators, and then be communicated to all participants, whereby further consent will be obtained for any protocol amendments.

20. Confidentiality

Participant data will be identified by a code number that will be allocated after the participant gives consent to participate in the study. The key linking the participant's identity to the relevant code will be stored in a password encrypted file that will not be accessible from the internet. Storage of the data collected will adhere to the University regulations & the Australian Code for the Responsible Conduct of Research. A dataset containing individual participant data will be published online in conjunction with the academic publication of these data. That dataset will be non-identifiable and will not contain any personal information about the participant that could be used to identify them (including age, gender, ethnicity, address or postcode). In any publication and/or presentation, information will be provided in such a way that participants cannot be identified, except with their written, informed permission. Any information obtained for the purpose of this research that could identify participants will be treated as confidential and securely stored.

21. Declaration of Interests

None of the investigators have any pecuniary interest or academic conflict of interests in the outcomes of this study.

22. Access to data

During the study only investigators and members of the study team will have access and control to any data collected from participants. There are no contractual agreements that would limit access or control of the study to the investigators. After the study, a non-identified dataset will be made available online in a data repository. Making data available in such a way is increasingly becoming an expectation of research teams who conduct publicly funded research.

23. Ancillary and post-trial care

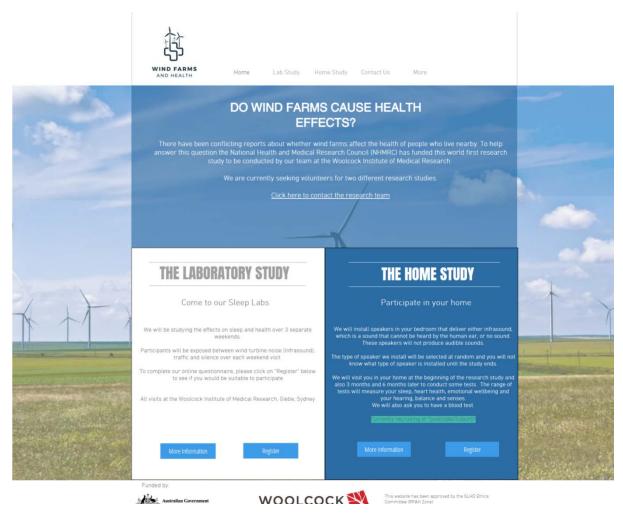
As this is not a clinical trial for a medical condition and does not involve any treatment, no clinical follow up will be routinely offered to participants. If however any harm is caused during this protocol or a medical condition becomes apparent, then medical follow-up will be arranged with either a member of the clinical research team or the participant's normal medical practitioner.

24. Dissemination policy

Study results will be published in peer-reviewed journals and participants will be made aware of these following publication should they desire. The publication committee consists of Prof Marks & Grunstein, A/Prof Marshall and Drs Toelle and Tonin. They shall be responsible for the formulation and execution of publication plans. Authorship on any manuscripts will be at the discretion of the publication committee.

25. Appendix

A. Online Registration and Consent forms



I. <u>www.windfarmstudy.com</u>





Frequently Asked Questions

1. What is the Woolcock Institute of Medical Research?

The Woolcock Institute is an inter-disciplinary research institute dedicated to understanding and treating respiratory and sleep disorders. With over 200 research and clinical professionals, we are a world leader in the area of research, clinical diagnosis and treatment. We are affiliated with the University of Sydney. The Woolcock Institute is located at 431 Glebe Point Road in the Suburb of Glebe in Sydney, NSW, Australia.

2. What is the Purpose of this study?

Communities living near wind turbines have presented with a cluster of health symptoms sometimes called "Wind Turbine Syndrome". The National Health and Medical Research Council of Australia (NHMRC) have recently conducted a thorough review and did not find any scientifically robust studies that could definitively prove or disprove whether wind turbine noise causes human ill-health. Wind turbines generate noise that is below the audible range for humans (called infrasound) and nobody has yet conducted a scientific study in the community to determine whether it has any effects on humans. The purpose of this study is to investigate whether 6 months of wind turbine simulated infrasound has effects on human health measures when compared to no sound.

3. Am I eligible to participate in this study?

Eligible participants are adults with normal hearing who report they are at least somewhat sensitive to noise and are willing to have speakers installed into their bedroom for 6 months. Our online screening questionnaire will determine whether you meet the full eligibility criteria.

4. What will the research involve?

This study will require installation of 4 x 600mm cube speakers into your bedroom. People will be randomly allocated to receive infrasound speakers or no sound speakers. Because infrasound cannot be heard you will not know which speakers

you have installed in your bedroom. These speakers will run for the 6 months of the study. Three times during this six months we will visit you at home to collect a range of health-related measurements (sleep, brain activity, reaction time, memory, heart rate and blood samples etc.).

5. Will I get paid for participating in this research?

We will reimburse you for the cost of electricity to power the speakers and in addition you will be reimbursed for your time. We will reimburse you \$500 at 3 and 6 month visits.

6. What are the benefits of this study?

There are no direct benefits to you by participating in this study. You may learn some interesting things about your sleep and other health measurements which you will be able to see on request. Your participation in this study will help in guiding future public policy about the health effects of wind turbines and traffic noise.

If you have any other questions or queries, please contact windfarmHomestudy@woolcock.org.au or call 9114 0493

III. Online Screening Consent Forms

Consent

select a partcipant... Remove

Dear Sir/Madam,

This questionnaire was developed by the Woolcock Institute of Medical Research.

The Wind Farm study is exclusively funded by the Australian Commonwealth through the National Health and Medical Research Council (NHMRC) and aims to study the impact of noise exposures on sleep and health including the inaudible sound that is produced by wind turbines called 'infrasound'

This important research is impossible without the generous contributions from volunteers and such we would like to invite you to contribute to this research effort designed to better understand the effects of Wind farms on health including sleep. We would be grateful if you would complete the following questionnaires that will take up to 30 minutes. Please complete all sections unless it states that you are not required to do so.

Taking part in this research is completely voluntary and all information obtained in this questionnaire will be kept confidential and de-identified prior to any research use. Any research information will be de-identified and stored completely anonymously and separate from your personal information on a Wind Farms database with same high level of security as your personal medical record. Your information will not be provided to any third party unless required by law.

If you have any concerns or questions we encourage you to contact our research team on Windfarmstudy@woolcock.org.au

I have read and understood the above information and:

Please selec

Yes, I agree to participate in this research study and I understand that I may be contacted and invited to participate in future stages of screening if suitable

No, I do not wish to take part in this or future research

By selecting 'Yes', you are stating that you understand the information provided and give consent for your de-identified responses to be used for research purposes.

- You understand that your participation in this research study is entirely voluntary
- You are under no obligation to participate and you can withdraw at any time
- · You also understand that all data collected under this research study is strictly confidential.

Save & Back

Thank you for completing our questionnaires for the Wind Farms study at the Woolcock Institute of Medical Research.

If you are eligible to continue to the next stages of the study, a member from the research team will be in contact you to arrange a home visit to do a hearing test.

Prior to this visit, a watch like device will be sent to you called an actiwatch and a sleep diary which we will require you to wear 7 days before your home visit.

All tests during the screening visit are safe and non-invasive, although unlikely, some tests may feel uncomfortable at times

If you have any questions, please send an email to windfarmhomestudy@woolcock.org.au

Actiwatch



Sleep Diary

| tuntoniutun tuntari Karolinska Diary - Plesse Jil is | eggt evening | | | | LCOCI |
|---|--------------------|------|------|----------|----------------------|
| Date: | | Nigh | 6.6 | 11303 | |
| TOUR HALLMAN COLUMN TO A | Hours | Mins | Comm | annets . | |
| terhal time did you get into bed? | 110000 | | 100 | | |
| What time did you attempt sleep? | | | | | |
| How long did it take to full eclesy? | | | | | |
| Time of Final Avakening | | | | | |
| Time of getting out of bed | | | | | |
| row long did you steep? | | | | | |
| | CHRILEANU | MEER | | | |
| tive that you sleep? | 2 - yeary well | | . 9 | 2 | 1 - very poorly |
| realing refreshed after assisting | 5 - completely | 4 | .9 | 1.0 | 1 - not at all |
| alm steep | 5 - yery calm | 1.4 | - 3 | 2 | 1 - yeary despites |
| Sept Through | 5 - yes | | | 1.0 | t-woke too nerty |
| tase of Waking up | 5 - yery easy | 1.4 | 9 | | 3 - very difficult |
| tiese of falling extent | 5 - very easy | | | | 1- very difficult |
| Amount of Oreaming | 3 = much | | 1 | 1 | \$1 masse |
| tage per day (yesterday) | Number - | | | | |
| Caffeinated drinks yesterday ites. roffee, cola drinks, chacolate) | Number - | | | | |
| Aboliol yesterday inumber of standard drovins | Number - | . 7 | | 97. 7 | x 20 |
| those strongs did you hard during the day (yesterday) | 5 - very slengy | | | 3 | In not diverge at al |

Audiometry:

Responding to tones or words being played through headphones by pressing a button or repeating the word respectively.

- Yes, I hereby agree if eligible for the next stages to be contacted by a member of the research team to arrange a home visit to have a hearing test and to be sent an actiwatch and a sleep diary to wear before this home visit
- No, I do not wish to take part in this research study

B Questionnaires

I. Weinstein's Noise Sensitivity (WNS) Scale



II. <u>Insomnia Severity Index (ISI) questionnaire</u>

| I | nsomnia Se | verity In | dex | | |
|---|--|--|---|--------------------------------------|--|
| select a partcipant | | | | | Remov |
| For each question, please click on the numb | er that best describe | s your answer. | | | |
| 1. Please rate the CURRENT (i.e. LAST 2 | WEEKS) SEVERITY | of your inson | nnia problem(s |). | |
| | None | Mild | Moderate | Severe | Very Severe |
| a. Difficulty falling asleep | 0 | 1 | 2 | 3 | 4 |
| o. Difficulty staying asleep | 0 | 1 | 2 | 3 | 4 |
| . Problem waking up too early | 0 | 1 | 2 | 3 | 4 |
| 2. How SATISFIED/DISSATISFIED are y | ou with your CURR | ENT sleep pat | ttern? | | |
| , | Very Satisfied | Satisfied | Neutral | Dissatisfied | Very Dissatisfied |
| | | | | | |
| | 0 | 1 | 2 | 3 | 4 |
| | sleep problem to I | NTERFERE wit | h your daily fu | nctioning (e.g. | daytime |
| | sleep problem to I rk/daily chores, co | NTERFERE wit | h your daily funemory, mood, | nctioning (e.g. etc.) CURRENTI | daytime Y? |
| | sleep problem to I | NTERFERE wit | h your daily fu | nctioning (e.g. | daytime Y? Very Much |
| | sleep problem to I rk/daily chores, co Not at all | NTERFERE wit | h your daily funemory, mood, | nctioning (e.g. etc.) CURRENTI | daytime Y? Very Much |
| fatigue, mood, ability to function at wo | sleep problem to I rk/daily chores, co Not at all Interfering | NTERFERE with ncentration, n A Little | h your daily funemory, mood, o | nctioning (e.g. etc.) CURRENTI Much | daytime Y? Very Much Interfering |
| atigue, mood, ability to function at wo | sleep problem to I rk/daily chores, co Not at all Interfering | NTERFERE with ncentration, n A Little | h your daily funemory, mood, o | nctioning (e.g. etc.) CURRENTI Much | daytime Y? Very Much Interfering 4 your life? Very Much |
| fatigue, mood, ability to function at wo | sleep problem to II rk/daily chores, cor Not at all Interfering O nk your sleep prob Not at all | NTERFERE with ncentration, not a Little | h your daily furnemory, mood, or Somewhat | Much 3 the quality of y | daytime Y? Very Much Interfering 4 your life? Very Much |
| fatigue, mood, ability to function at wo | sleep problem to II rk/daily chores, cor Not at all Interfering O nk your sleep prob Not at all Noticeable | NTERFERE with accentration, in A Little 1 lem is in term A Little 1 | h your daily furnemory, mood, of Somewhat 2 as of impairing Somewhat | Much Much Much | daytime Y? Very Much Interfering 4 your life? Very Much Noticeable |
| 3. To what extent do you consider your fatigue, mood, ability to function at wo | sleep problem to II rk/daily chores, cor Not at all Interfering O nk your sleep prob Not at all Noticeable | NTERFERE with accentration, in A Little 1 lem is in term A Little 1 | h your daily furnemory, mood, of Somewhat 2 as of impairing Somewhat | Much Much Much | daytime Y? Very Much Interfering 4 your life? Very Much Noticeable |

Save & Back

III. Depression Anxiety and Stress Scale (DASS-21)

DASS - 21 select a partcipant... Remove Please read each statement and click on a number 0, 1, 2 or 3 which indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement. Applied to Applied to Applied to me to a me to some me very Did not considerable apply to me degree, or much, or degree, or a some of the most of the at all good part of time time time 1. I found it hard to wind down 2. I was aware of dryness of my mouth 3. I couldn't seem to experience any positive feeling at all 4. I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion) 5. I found it difficult to work up the initiative to do things 6. I tended to over-react to situations 7. I experienced trembling (eg, in the hands) 8. I felt that I was using a lot of nervous energy 9. I was worried about situations in which I might panic and make a fool of 10. I felt that I had nothing to look forward to 11. I found myself getting agitated 12. I found it difficult to relax 13. I felt down-hearted and blue 14. I was intolerant of anything that kept me from getting on with what I was 15. I felt I was close to panic 16. I was unable to become enthusiastic about anything 17. I felt I wasn't worth much as a person 18. I felt that I was rather touchy 19. I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat) 20. I felt scared without any good reason

Save & Back

21. I felt that life was meaningless

IV. Visual Analogue Scale for Symptom



We are also adding the following list of symptoms that are not typically associated with wind farm health complaints: stomach ache, sore jaw, hand tremble or shake.

V. Noise Annoyance Scale

| Noise Annoyance Scale | | | | | | |
|--|-----------------|--------------|--|--|--|--|
| select a partcipant | | Remove | | | | |
| Please click along the line in which best describes your current annoyance with the noise. | | | | | | |
| | NOISE ANNOYANCE | | | | | |
| Not Annoyed | | Very Annoyed | | | | |

VI. Warwick Edinburgh Mental Well-being Scale

The Warwick-Edinburgh Mental Well-being Scale (WEMWBS) Remove select a partcipant... Below are some statements about feelings and thoughts. Please tick the box that best describes your experience of each over the last 2 weeks None of the Some of the Often Rarely All the time time time 1. I've been feeling optimistic about the future 2. I've been feeling useful 3. I've been feeling relaxed 4. I've been feeling interested in other people 5. I've had energy to spare 6. I've been dealing with problems well

Save & Back

7. I've been thinking clearly

10. I've been feeling confident

12. I've been feeling loved

14. I've been feeling cheerful

8. I've been feeling good about myself

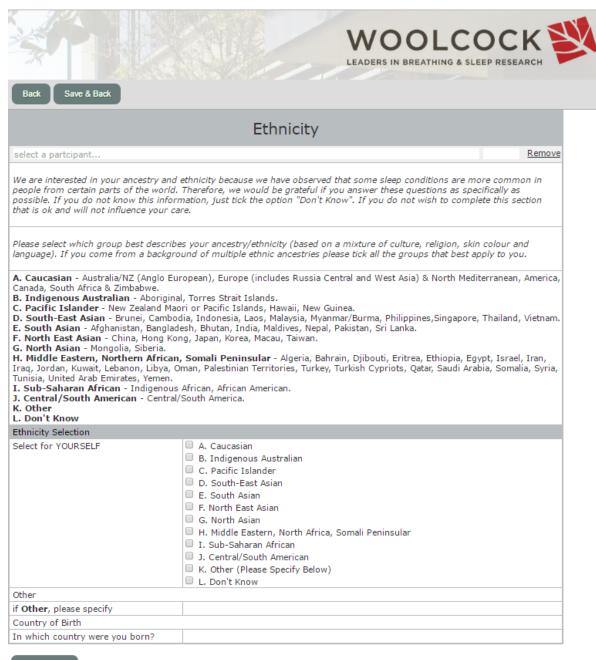
13. I've been interested in new things

9. I've been feeling close to other people

11. I've been able to make up my own mind about things

C. <u>Online Screening- Ethnicity, Lifestyle, Medical History, Medication, Sleep disorders and patterns and Attitudes on Wind farms.</u>

I. Ethnicity



Save & Back

II. <u>Lifestyle</u>

| | Lifestyle | | |
|---|-------------------------------|--|---|
| select a partcipant | | Remove | |
| General Health | | | |
| How would you describe your general | Excellent | | |
| health? | Very Good | | |
| | Good | | |
| | Fair | | |
| | Poor | | |
| Dhariaal Askinika | Pool | | |
| Physical Activity How often, on average, do you do at | Never | | |
| least 30 minutes of moderate physical | | | |
| activity - like walking? | Sometimes | | |
| | A couple of days a week | | |
| | Most days a week | | |
| | Everyday | | |
| Smoke | | | |
| Do you think you will be able to go 3 weekends without smoking? | No Yes | | |
| Have you ever smoked? | No Yes | | |
| Do you or did you smoke regularly? | | | |
| ("No" means less than 20 packs in a lifetime or less than 1 cigarette per day for 1 year). | No Yes | | |
| If you previously smoked but have stopped, in which year did you last smoke? | | | |
| How old were you when you <u>first</u> <u>started regular</u> cigarette smoking? On average, over the entire time you | | | |
| smoked, how many cigarettes did you smoke <u>each day</u> ? | | | |
| Do you think you will be able to go 3 | No Yes | | |
| weekends without alcohol? | | | |
| In a typical week during the past year, on how many days did you consume an | 0 days / do not drink alcohol | | |
| alcoholic drink of any type? Please check the appropriate answer. | 1 day | | |
| check the appropriate answer. | 2 days | | |
| | 3 days | | ı |
| | 4 days | | |
| | 5 days | | |
| | 6 days | | |
| | 7 days | | |
| On days when you drink alcohol, how | Workday(s) | C-#-: | |
| many standard drinks of beer, wine / or | None | Caffeine Do you think you will be able to go 3 | |
| other type of alcohol would you have? (<u>Click here</u> for list of standard drinks) | 1-2 drinks | weekends without caffeine? | |
| Please check the appropriate answer. | 3-5 drinks | In a typical day during the past week, how many caffeinated drinks did you | |
| | 6-9 drinks | have e.g. coffee, tea, coca cola, hot | |
| | | chocolate, energy drinks, soft drinks, ice teas? (If you're unsure whether | |
| | 10 or more drinks | your drink contains caffeine <u>click here</u> to find out.) Please check the | |
| | Non-workday(s) | appropriate answer. | |
| | None | | |
| | 1-2 drinks | | |
| | 3-5 drinks | | |
| | 6-9 drinks | | |
| | 10 or more drinks | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | How many hours before bedtime would | |
| | | you normally have your last drink containing caffeine? | |
| | | | |
| | | Save & Back | |

III. Medical history

Remove.

<u>Keep for Screening:</u> Anxiety disorder, bipolar disorder, depression, post-traumatic stress disorder (PTSD), Other (psychiatric disease- please specify)

Keep for post enrolment questionnaire: Angina or Chest Pain from Heart conditions, Atrial fibrillation, Asthma, Coronary bypass, coronary angioplasty or stent insertion, congestive heart failure, Diabetes, Elevated Cholesterol, Eye disorder or disease, High blood pressure (hypertension), Implant or cardiac pacemaker, motor neuron disease, multiple sclerosis, muscular dystrophy, myocardial infarction (heart attack), Stroke (CVA), Other (heart disease- please specify), Other (major surgery-please specify, Any history of loss of consciousness- please specify.

<u>IV.</u>

| Medical History | | | | | | | |
|--|----------------------------------|----------------------------------|--|--|--|--|--|
| select a partcipant | | Remov | | | | | |
| 1. Have you <u>ever</u> had any of these <u>doctor-diagnos</u> If yes, how <u>old were you</u> when <u>first</u> diagnosed? | sed illnesses o | or procedures? | | | | | |
| Please read through the list of medical conditions in the conditions that you were diagnosed with and your age | he table below at the time of | and tick only thos diagnosis. | | | | | |
| Illness or Proceedure | Tick if diagnosed | Age of diagnosis | | | | | |
| Adenoidectomy (adenoids surgically removed) | | | | | | | |
| Alcohol abuse | | | | | | | |
| Anaemia | | | | | | | |
| Angina or chest pain from a heart condition | | | | | | | |
| Anxiety disorder | | | | | | | |
| Arthritis | | | | | | | |
| Atrial fibrillation | | | | | | | |
| Attention deficit disorder | | | | | | | |
| Asthma | | | | | | | |
| Auditory defects or hearing impairments | | | | | | | |
| Bipolar Disorder | | | | | | | |
| Cancer Please specify: | | | | | | | |
| Carotid surgery (either endarterectomy or stent) | | | | | | | |
| Chronic back or neck pain | | | | | | | |
| Chronic bronchitis | | | | | | | |
| Chronic fatigue syndrome | | | | | | | |
| Cirrhosis of the liver | | | | | | | |
| Colour blindness | | | | | | | |
| Coronary bypass | | | | | | | |
| Coronary angioplasty or stent insertion | | | | | | | |
| Congestive heart failure | | | | | | | |
| Depression | | | | | | | |
| Diabetes | | | | | | | |
| Elevated cholesterol | | | | | | | |
| Emphysema or Chronic Obstructive Pulmonary Diseas (COPD) | e | | | | | | |
| Erectile dysfunction | | | | | | | |

| Eye disorder or disease | |
|---|--|
| Gastric or duodenal ulcer | |
| Gastro-oesophageal reflux (heartburn) | |
| Gout | |
| Hay fever | |
| Hepatitis | |
| High blood pressure (hypertension) | |
| Implant of cardiac pacemaker | |
| Inflammatory bowel disease (including Crohn's Disease and Ulcerative Colitis) | |
| Kidney failure | |
| Kidney stones | |
| Liver disease | |
| Motor neurone disease | |
| Multiple sclerosis | |
| Muscular dystrophy | |
| Myocardial infarction (heart attack) | |
| Nose with a deviated septum | |
| Osteoporosis | |
| Parkinson's disease | |
| Peripheral vascular disease of legs or claudication | |
| Pneumonia | |
| Polycystic ovarian syndrome | |
| Poliomyelitis | |
| Post-Traumatic Stress Disorder | |
| Sinus disease | |
| Stroke (CVA) | |
| Thyroid disease | |
| Transient ischemic attack (TIA) | |
| Tonsillectomy | |
| Other psychiatric disease Please specify: | |
| Other heart disease Please specify: | |
| Any history of a loss of consciousness Please specify: | |
| Other major surgery Please specify: | |

Medications

REMOVE

| | | Medication |
|----------------------------|----------------------|--|
| select a partcipa | nt | Remove |
| 1. Do vou take pr | escribed medicati | ons to help you sleep? |
| not at all | | , |
| occasionall | y (1-2 times per n | nonth) |
| sometimes | (3-4 times per mo | onth) |
| often (1-2 t | imes per week) | |
| frequently | (3 or more times p | per week) |
| 2. Do you take ot | her medications (i | including herbal or other supplements) to help you sleep? |
| not at all | | |
| occasionall | y (1-2 times per n | nonth) |
| sometimes | (3-4 times per mo | onth) |
| often (1-2 t | imes per week) | |
| frequently | (3 or more times p | per week) |
| | e last section of th | you currently take. If any of your medications are not listed below please list these his question |
| Taken in the | Currently | |
| past 6 months | taken | Name |
| | | Aspirin (e.g. Solprin, Aspro, Disprin) |
| | | Fentanyl (e.g. Actiq Lozenge, Durogesic Patches) |
| | | Hydromorphone (e.g. Dilaudid) |
| | | Ibuprofen (e.g. Nurofen, Advil) |
| | | Ibuprofen-codeine (e.g. Chemists' Own Ibuprofen Plus Codeine, Nurofen Plus) |
| | | Morphine (e.g. Anamorph, Kapanol, MS Contin, MS Mono) |
| | | Oxycodone (e.g. Endone, OxyContin, OxyNorm, Targin) |
| | | Paracetamol (e.g. Panadol, Panamax) |
| | | Paracetamol-codeine (e.g. Codalgin, Mersyndol, Panadeine, Chemists' Own Pain Relief) |
| | | Tramadol (e.g. Lodam, Tramal, Zydol) |
| Cold and Flu med | ications | |
| Taken in the past 6 months | Currently taken | Name |
| | | Antihistamine |
| | | Pseudoephedrine (e.g. Benadryl, Chemists' Own Cold & Flu, Codral, Demazin, Sudafed Sinus) |

Keep section 1. and 2. for screening: Sleep and anti-anxiety medication list from section 3. only. Change the tick boxes to (Taking/taken in the last month)

Add: Free text to allow listing medications they take when asked during baseline home visit.

| Anti-inflammatory | / medication | | | | |
|----------------------------|--------------------|--|--|--|--|
| | | Betamethasone (e.g. Antroquoril) | | | |
| | | Celecoxib (e.g. Celebrex) | | | |
| | | Diclofenac (e.g. Voltaren) | | | |
| | | Indomethacin (e.g. Indocid) | | | |
| | | Meloxicam (e.g. Melox, Movalis, Mobic) | | | |
| | | Naproxen (e.g. Anaprox, Inza, Naprogesic) | | | |
| | | Prednisolone (e.g. Panafcortelone) | | | |
| | | Prednisone (e.g. Panafcort) | | | |
| Sleep and Anti-ar | wists madientia | • | | | |
| Taken in the past 6 months | Currently taken | Name | | | |
| | | Alprazolam (e.g. Xanax, Kalma) | | | |
| | | Clonazepam (e.g. Rivotril, Paxam) | | | |
| | | Diazepam (e.g. Valium, Antenex, Ducene) | | | |
| | | Flunitrazepam (e.g. Hypnodorm) | | | |
| | | Lorazepam (e.g. Ativan) | | | |
| | | Melatonin (e.g. Circadin) | | | |
| | | Nitrazepam (e.g. Mogadon, Alodorm) | | | |
| | | Oxazepam (e.g. Serepax, Alepam, Murelax) | | | |
| | | Temazepam (e.g. Normison, Temaze, Temtabs, Euhypnos) | | | |
| | | Zopiclone (e.g. Imovane) | | | |
| | | Zolpidem (e.g. Stilnox) | | | |
| Anti-depressants | | | | | |
| Taken in the past 6 months | Currently taken | Name | | | |
| | | Agomelatine (e.g. Valdoxan) | | | |
| | | Citalopram (e.g. Cipramil, Talam) | | | |
| | | Escitalopram (e.g. Lexapro, Lexam) | | | |
| | | Fluoxetine (e.g. Prozac, Lovan) | | | |
| | | Lithium (e.g. Lithicarb, Quilonum) | | | |
| | | Mirtazapine (e.g. Avanza, Axit) | | | |
| | | Paroxetine (e.g. Aropax) | | | |
| | | Sertraline (e.g. Zoloft) | | | |
| | | Venlafaxine (e.g. Efexor) | | | |

| | | | Cholester | ol medications | | | | | |
|-----------------------------------|--------------------------------|---|----------------------|----------------------------------|--------------------------|----------|---|--------|--|
| | | | Taken ir past 6 m | | rently ken | Name | | | |
| | | | | (| | Atorva | orvastatin (e.g. Lipitor) | | |
| | | | | (| | Ezetin | nibe / Atorvastatin (e.g. Atozet) | | |
| Restless Legs or F | Parkinson's Diseas | se medications | | Antibiotic medic | 1 | | | | |
| Taken in the past 6 months | Currently taken | Name | | Taken in the past 6 months | Curren taker | tly n | Name | - | |
| | Caken | Benztropine (e.g. Benztrop, Cogentin) | | | | | Amoxycillin (e.g. Amoxil, Alphamox) | | |
| | | Bromocriptine (e.g. Kripton, Parlodel) | | | | | Amoxycillin / Clavulanic Acid (e.g. Augmentin Duo) | | |
| | | Cabergoline (e.g. Cabaser, Bergoline) | | | | | Cephalexin (e.g. Keflex, Cilex) Chloramphenicol eye (e.g. Chlorsing eye drops) | - | |
| | | Gabapentin (e.g. Gabatine, Neurontin, Gabahexol) | | | | | Roxithromycin (e.g. Biaxsig, Roxar, Roximycin) | ١ | |
| | | Hyoscyamine (e.g. Donnatab) | | Gastrointestinal | System med | ications | | | |
| | | Levodopa (e.g. Madopar, Sinemet) | | Taken in the past 6 months | Curren | tly | - Name | 7- | |
| | | Phenytoin (e.g. Dilantin) | | | | | Esomeprazole (e.g. Nexium) | _ | |
| | | Pramipexole (e.g. Sifrol) | | | | | Omeprazole (e.g. Losec, Acimax) | | |
| | | Ropinirole (e.g. Repreve, Appese) | | | | | Pantoprazole (e.g. Somac) | _ | |
| | | Other Restless Legs or Parkinson's disease medication | ns cont. | | | | Rabeprazole (e.g. Pariet) | | |
| | Selegiline (e.g. Eldepryl) | | | | | | Ranitidine (e.g. Zantac) | | |
| | . , . | | | Blood glucose lo Taken in the | wering medic Curren | | | | |
| Epilepsy medicati Taken in the | ons (some also us Currently | sed for pain) | | | past 6 months taken Name | | Name | | |
| past 6 months | taken | Name | | | | | Gliclazide (e.g. Diamicron) | _ - | |
| | | Carbamazepine (e.g. Tegretol) | | | | | Insulin (e.g. Novorapid, Humalog, Actrapid, Humulin, Mixtard, Novomix, Levemir, Lantus) | _ | |
| | | Ethosuximide (e.g. Zarontin) | | | | | Metformin (e.g. Diabex, Diaformin) | - - | |
| | | Phenobarbitone | | | | | Metformin / Glibenclamide (e.g. Glucovance) | | |
| | | Gabapentin (e.g. Gabatine, Neurontin, Gabahexol) | | | | | Pioglitazone (e.g. Actos) Rosiglitazone (e.g. Avandia) | - | |
| | | Lamotrigine (e.g. Lamictal, Lamogine) | | | | | Rosigillazone (e.g. Avantila) | _ | |
| | | Phenytoin (e.g. Dilantin) | | Oral Contracept | 1 | - |) | | |
| | | | | Taken in the past 6 months | Curren taker | tly n | Name | | |
| | | Pregabalin (e.g. Lyrica) | | | | | Cyproterone / Ethinyloestradiol (e.g. Brenda, Diane, Estelle, Juliet) | | |
| | | Primidone (e.g. Mysoline) | | | | | Drospirenone / Ethinyloestradiol (e.g. Yasmin, Yaz) | | |
| | | Sodium valproate (e.g. Epilim, Valpro) | | | | | Levonorgestrel / Ethinyloestradiol (e.g. Levlen, Microgynon, Logynon, Trifeme, Triphasil) | | |
| | | Tiagabine (e.g. Gabitril) | | Other medicatio | | | | 4 | |
| Thyroid Deficiency | y medication | | | Taken in the past 6 months | Curren taker | | Name | | |
| Taken in the past 6 months | Currently taken | Name | | | | | Topical steroids | | |
| | | Thyroxine (e.g. Eutroxsig, Oroxine) | | | | | Other hormonal contraception | | |
| ' | | | | | | | Sex steroids (for males only) | _ | |
| | | | | | | | Any health food supplements or herbal remedies | | |
| | | | | If you take an | / medication | ns whi | ch are not listed above, please specify these below. | \neg | |
| | | | | | | | | 4 | |

Save & Back

V. Sleep Disorders and Patterns

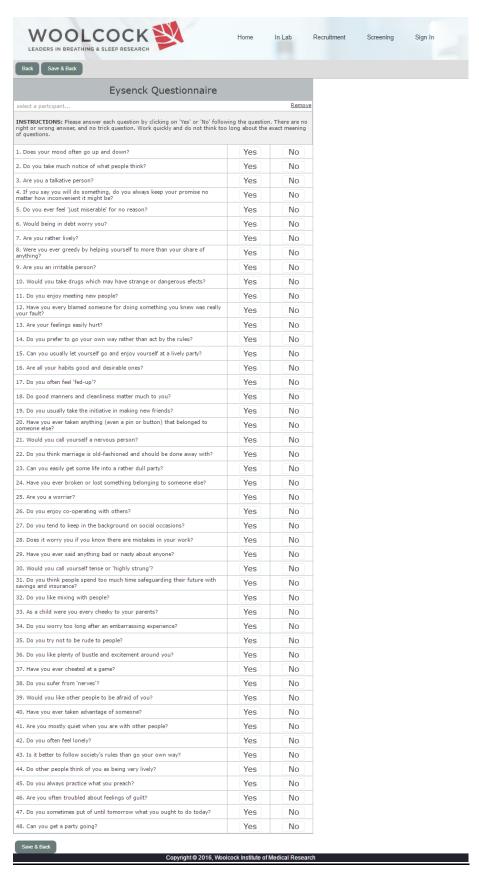
| | | | | | Insomnia | | | | |
|--|----------------|-------------------|--|-------------------------------|--|----------------|--|----------------|-----------------------------|
| Sleep Disorders & | Pattern | IS | | | If you selected 'Insomnia' as a diagnosed condition for question 1, were prescribed for your insomnia? (multiple selections allowed) | any of the fol | llowing treatm | nents recomm | ended or |
| select a partcipant | | | | Remove | If you select any of following treatments, please also indicate if you are stil | using this tre | eatment on a | regular basis | |
| 1. Have you been diagnosed with any of the following sleep conditions by a | doctor?. | | | | Are you still using this treatment of regular basis? | | | | |
| Please tick all that apply, | | | | | | Tick | Yes | No | Why Not |
| Sleep Apnea | | | Referral to psychologist / cognitive behavioural therapy (CBT) program | | | | | | |
| Insomnia | | | | | Referral to a psychiatrist | | | | |
| Narcolepsy | | | | | Lifestyle advice (e.g. diet, exercise, weight loss program) | | | | |
| Restless Legs or Periodic Leg Movements during Sleep | | | | | Medications prescribed by your doctor that help you sleep | | | | |
| Bruxism (teeth grinding) | | | | | Over the counter treatments / drugs not prescribed by your doctor (e.g. valerian, herbal remedies, magnesium, melatonin) | | | | |
| REM Behavioural Disorder | | | | | Acupuncture or hypnotherapy | | | | |
| Parasomnias (sleep walking, sleep talking, night terrors) | | | | | Meditation, yoga, and / or relaxation techniques | | | | |
| Obesity Hypoventilation Syndrome | | | | | Other | | | | |
| Delayed Sleep Phase Disorder | | | | | Waiting for treatment | | | | |
| I have not been diagnosed with any sleep condition | | | | | No treatment | | | | |
| Sleep Apnea | | | | | Other diagnosed condition | | | | |
| 2. If you selected 'Sleep Apnea' as a diagnosed condition for question 1, w prescribed for your sleep apnea? (multiple selections allowed) | ere any of the | following tre | atments rec | ommended or | For any other diagnosed condition, were any of the following treatments (multiple selections allowed) | recommende | ed or prescrib | ed for your co | indition? |
| If you select any of following treatments, please also indicate if you are still | using this tre | eatment on a | regular basi | s. | If you select any of following treatments, please also indicate if you are stil | using this tre | eatment on a | regular basis | |
| | | Are you st | till using this <u>reqular ba</u> | treatment <u>on a</u> sis? | | | Are you still using this treating regular basis? | | reatment <u>on a</u> is? |
| | Tick | Yes | No | Why Not | | Tick | Yes | No | Why Not |
| Continuous positive airway pressure (CPAP) machine | | | | | Lifestyle advice (e.g. developing good sleep habits, avoiding sleep deprivation) | | | | |
| Mandibular advancement splint, dental device or oral appliance | | | | | Referral to a psychiatrist | | | | |
| Lifestyle advice (e.g. diet, exercise, weight loss program) | | | | | Medications prescribed by your doctor | | | | |
| Medications prescribed by your doctor that help you stay awake (e.g. modafinil (Provigil, Modavigil), Ritalin, Amphetamine) | | | | | Other | | | | |
| Over the counter treatments or drugs not prescribed by your doctor (e.g. snore strips, snore sprays, snore rings) | | | | | Waiting for treatment | | | | |
| Positional treatments (e.g. tennis ball, something to stop you rolling on your back) | | $\overline{\Box}$ | | | No treatment | | | | |
| Other | | n | | | | | | | |
| Surgery | | | | | | | | | |
| Waiting for treatment | | | | | 1 | | | | |
| No treatment | | | | | | | | | |
| i. If you selected the 'Surgery' option in question 2, please specify the type | and year of s | surgery: Year | | | | | | | |
| Palatal surgery | I ICK | real | | | - | | | | |
| Tonsillectomy | | | | | - | | | | |
| Nose surgery | | | | | - | | | | |
| Laser treatment | | | | | - | | | | |
| Surgery for weight loss | | | | | 1 | | | | |
| Other | | | Ple | ase specify | | | | | |

VI. Epworth Sleepiness Scale (ESS)

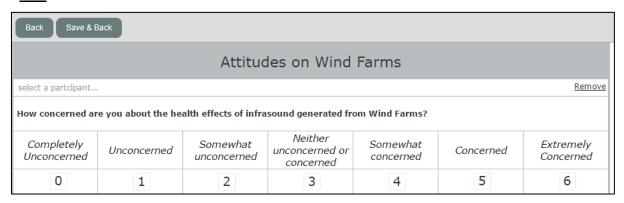
| | WOOL LEADERS IN BREATHI | | | W |
|--|-------------------------------|-------------------------------|---------------------------------|-----------------------------|
| Back Save & Back | | | | |
| | ESS | | | |
| select a partcipant | | | | Remove |
| How likely are you to doze or fall asleep in the follow to your usual way of life in recent times. Even if you out how they would have affected you. | | | | |
| | Would never doze | Slight chance of dozing | Moderate chance of dozing | High chance of dozing |
| | | | | |
| 1. Sitting and reading | | | | |
| Sitting and reading Watching TV | | | | |
| | ing) | | | |
| 2. Watching TV | ing) | | | |
| Watching TV Sitting, inactive in a public place (eg a theatre or a meeting). | | | | |
| Watching TV Sitting, inactive in a public place (eg a theatre or a meeti As a passenger in a car for an hour without a break | | | | |
| 2. Watching TV 3. Sitting, inactive in a public place (eg a theatre or a meeti 4. As a passenger in a car for an hour without a break 5. Lying down to rest in the afternoon when circumstances | | | | |

Save & Back

VII. EYSENCK Personality Questionnaire Revised (EPQ-R)



VIII. Attitudes on Wind Farms



<u>IX.</u>

D. Actiwatch and Sleep Diary

I. Actiwatch

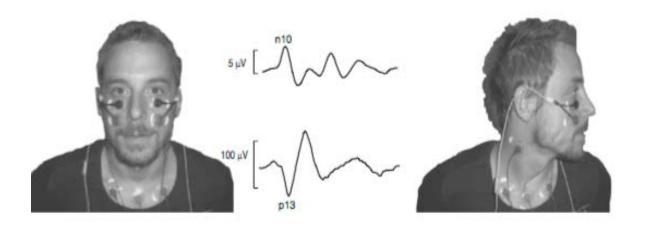


II. Sleep Diary

| | Day 1 |
|--|--|
| S1. Today's Date (dd/mm/yy) | Day I |
| S2. Time | hmin |
| S3. What time did you go to bed? | hmin |
| S4. What time did you attempt to fall asleep? | hmin |
| S5. How long did it take you to fall asleep? | hmin |
| S6. What time did you finally | hmin |
| S7. How long did you sleep? | hmin |
| S8. How long did you stay in bed before getting up? | hmin |
| S9. How many times did you awaken? List each: approximately when you woke and for how long. | Number of times: When?hmin Length?hmin |
| S10. Did anything disturb your sleep? [Yes I No] (check all that apply) | □ Noise □ Work Duties □ Thoughts on mind □ Toilet (#) □ Light □ Aches/Pains/Physical Discomfort □ Air Temperature □ Electronic Media (Phone/Email/SMS) □ Other: |
| S11. How would you rate your quality of sleep? | 1= Best Sleep ever 2 3 4 5 = Neither best nor worst sleep 6 7 8 9 = Worst Sleep ever |
| S12. Please indicate the number which best describes how sleepy you have felt in the preceding 5 minutes | 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 effort to stay awake 8 - sleepy but some effort to stay awake 9 - very sleepy, fighting sleep, great effort to stay awake |
| S13. Did you have any caffeine yesterday? [Yes / No] (indicate how much) | coffeecups teacups caffeinated soft drinkscans caffeine pills(100mg)(200mg |

| S14. Did you have any alcohol yesterday? [Yes / No] (indicate how much) | beer (375 ml glasses/bottles/cans) wine (150 ml glasses) spirits (30 ml nip) |
|---|--|
| S15. Did you exercise in the last 24 hours? | [Yes/No] How many times? When?hmin For how long?hmin How strenuous? (low, medium, high) |
| S16. Did you nap yesterday? [Yes / No] How many times? | [Yes / No] Nap starthmin |
| List each: when the nap started and when it ended | Nap end hmin |
| S17. Did you take sleeping pills to help you sleep? | [Yes/No] Was it Prescribed Over-the-counter |
| S18. How many times did you remove your activatch? | Number: Actiwatch removed at: hmin Put back on at: hmin |
| Comments | |

E. Neurootology



I. Vestibular Evoked Myogenic Potentials – Setup and Equipment

Mini Shaker Oscillator:



II. Video Head Impulse Test (VHIT)



III. Otoacoustic Emissions



IV. Pure tone Audiometer



V. Videonystagmography

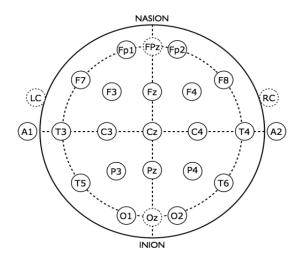


VI. Tympanometer

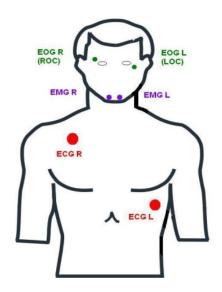


F. Polysomnography (PSG) setup

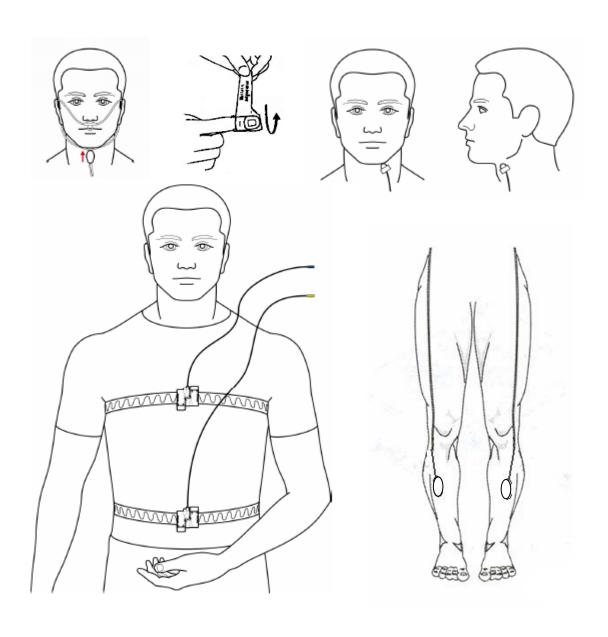
I. EEG setup



II. Additional ECG, EOG and EMG Chin electrode placements.

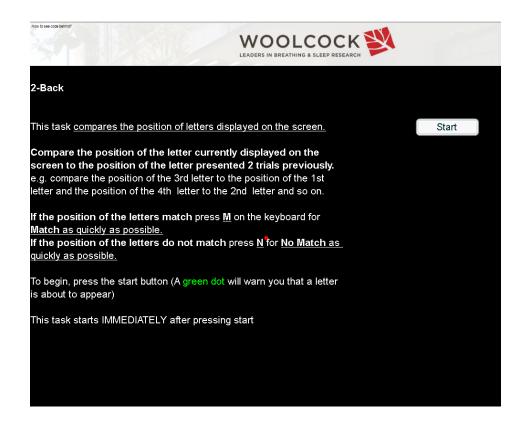


III. Additional PSG electrodes

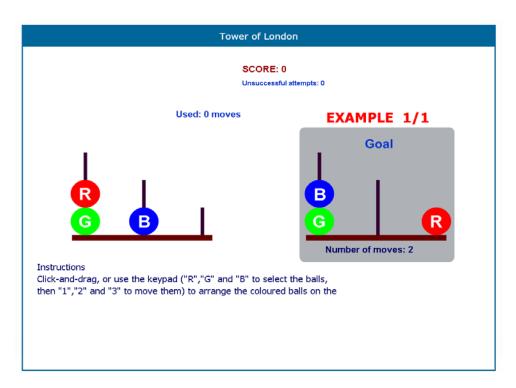


G. Neurocognitive Test

I. N-back (2-Back)



II. Tower of London



H. Cardiovascular and stress measures

SphygmaCor Xcel Device (Pulse Wave Velocity)



References

- 1. Pierpont N. Wind Turbine Syndrome. Santa Fe, NM: K-Selected Books; 2009.
- 2. Moller HL, M. A questionnaire survey of complaints of infrasound and low-frequency noise. Journal of Low Frequency Noise Vibration and Active Control. 2002;21(2):53-64.
- 3. Farboud, A., Crunkhorn, R., Trinidade, A. 'Wind turbine syndrome': fact or fiction? The Journal of laryngology and otology. 2013;127(3):222-6.
- 4. Jeffery RD, Krogh CM, Horner B. Industrial wind turbines and adverse health effects. Can J Rural Med. 2014;19(1):21-6.
- 5. Pedersen E. Health aspects associated with wind turbine noise–Results from three field studies. Noise Control Eng J. 2014;59(1):47-53.
- 6. Bakker RH, Pedersen E, van den Berg GP, Stewart RE, Lok W, Bouma J. Impact of wind turbine sound on annoyance, self-reported sleep disturbance and psychological distress. Sci Total Environ. 2012;425:42-51.
- 7. Babisch W. The Noise/Stress Concept, Risk Assessment and Research Needs. Noise Health. 2002;4(16):1-11.
- 8. Laszlo HE, McRobie ES, Stansfeld SA, Hansell AL. Annoyance and other reaction measures to changes in noise exposure a review. Sci Total Environ. 2012;435-436:551-62.
- 9. Salt ANK, J.A. Infrasound from wind turbines could affect humans. Bull Sci Technol Soc. 2011;31:296-302.
- 10. Tonin R. Sources of Wind Turbine Noise and Sound Propagation. Acoustics Australia. 2012;40(1).
- 11. Walker BH, G.; Hessler, D.; Rand, R.; Schomer, P. A Cooperative Measurement Survey and Analysis of Low Frequency and Infrasound at the Shirley Wind Farm in Brown County, Wisconsin. Wisconsin. PSCo, editor 2012.
- 12. Foundation. W. Acoustic Engineering Investigation at Cape Bridgewater Wind Facility 2015 [cited 2015 May 4]. Available from:

 http://waubrafoundationorgau/resources/acoustic-engineering-investigation-at-cape-bridgewater-wind-facility/. 2015.
- 13. NHMRC. Information Paper: Evidence on Wind Farms and Human Health. In: Council NHMRC, editor. Canberra 2015.
- 14. Salt AN, DeMott JE. Longitudinal endolymph movements and endocochlear potential changes induced by stimulation at infrasonic frequencies. J Acoust Soc Am. 1999;106(2):847-56.
- 15. Salt AN, Lichtenhan JT, Gill RM, Hartsock JJ. Large endolymphatic potentials from low-frequency and infrasonic tones in the guinea pig. J Acoust Soc Am. 2013;133(3):1561-71.
- 16. Parker D. Effects of Sound on the Vestibular System. Miami University; Oxford, Wright Patterson Airforce Base, Ohio;1976.
- 17. Macdougall HG, McGarvie LA, Halmagyi GM, Curthoys IS, Weber KP. The video Head Impulse Test (vHIT) detects vertical semicircular canal dysfunction. PLoS One. 2013;8(4):e61488.
- 18. Minor LB, Cremer PD, Carey JP, Della Santina CC, Streubel SO, Weg N. Symptoms and signs in superior canal dehiscence syndrome. Ann N Y Acad Sci. 2001;942:259-73.
- 19. Nivison ME. The relationship between noise as an experimental and environmental stressor, psychological changes, and psychological factors. Bergen: University of Bergen1992.
- 20. Taylor SM. A path model of aircraft noise annoyance. Journal of Sound and Vibration. 1984;96(243-60).
- 21. Luz G. Noise Sensitivity Rating of Individuals. Sound and Vibration. 2005.
- 22. Job RF. Noise sensitivity as a factor influencing human reaction to noise. Noise Health. 1999;1(3):57-68.

- 23. McCunney RJ, Mundt KA, Colby WD, Dobie R, Kaliski K, Blais M. Wind turbines and health: a critical review of the scientific literature. J Occup Environ Med. 2014;56(11):e108-30.
- 24. Marks A, Griefahn B. Associations between noise sensitivity and sleep, subjectively evaluated sleep quality, annoyance, and performance after exposure to nocturnal traffic noise. Noise Health. 2007;9(34):1-7.